Fra ide til protokoll – hvordan komme i gang?

Silje Watterdal Syversen MD PhD
Center for treatment of Rheumatic and Musculoskeletal Diseases (REMEDY)
Diakonhjemmet sykehus

Innhold

- Eksempler – fra ide til protokoll
- Problemstilling
  - Klinisk relevans
  - Pasientgrunnlag
  - Nytteverdi
- Praktisk ved prosjektstart
  - Forankring i sykehuset og i klinisk drift
  - Ressurser (personale, tid)
  - Forfatterskap/vitenskapelig samarbeid
- Prosjektskisse

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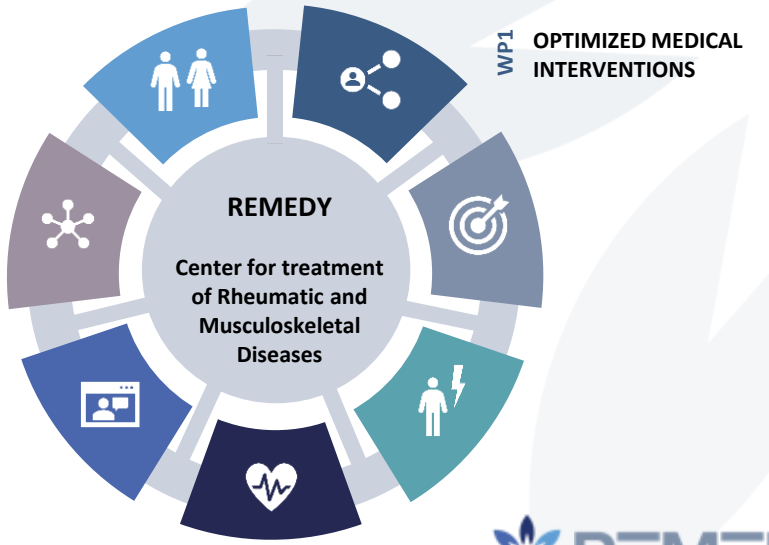
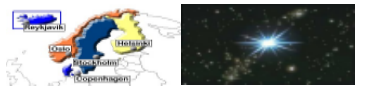
Forskningsmiljø

- Diakonhjemmet sykehus
- Klinikk for revmatologi, poliklinikk og forskning
  - Ansvar for artritt-sykdommer i Oslo
  - Regionale og nasjonale funksjoner
- REMEDY senteret
  - Hovedfokus på klinisk forskning

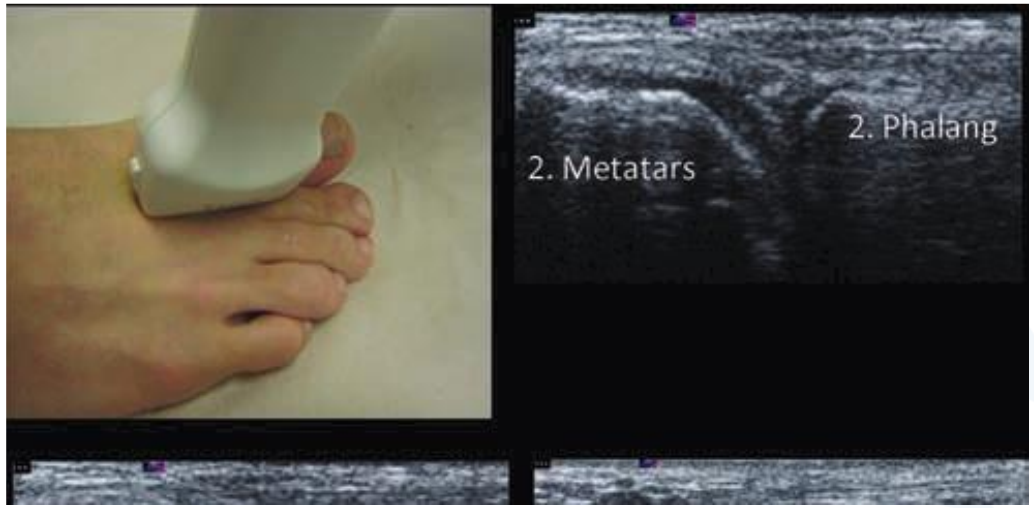


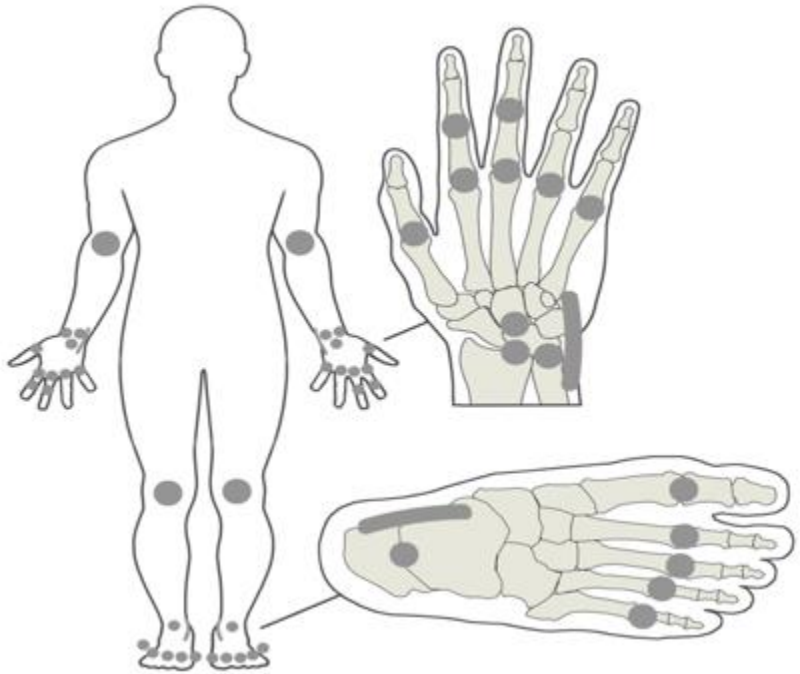
Forskerinitierte studier

ARCTIC – THE ARCTIC TRIAL	Randomized clinical trial in early rheumatoid arthritis assessing management with and without ultrasound	thebmj
NOR SWITCH	Randomized clinical trial of switch from innovator infliximab to biosimilar infliximab	THE LANCET
 NORD-STAR	Nordic randomized clinical trial in early rheumatoid arthritis comparing conventional therapy versus three biologic treatments	thebmj
ARCTIC REWIND	Randomized clinical trial in rheumatoid arthritis assessing withdrawal of disease-modifying drugs	JAMA
NOR DRUM – The Norwegian drug monitoring study	Randomized clinical trial assessing the effectiveness of targeting infliximab treatment by therapeutic drug monitoring versus routine care	JAMA

Eksempel: Ide

- **2000-tallet:** Ultralyd øker i bruk i revmatologisk praksis
- Studier viser sammenheng mellomsubklinisk inflammasjon påvist med ultralyd og leddskade samt sykdomsoppbluss ved RA
- Økt fokus på definerte behandlingsmål





Ref: Hammer HB et al, ARD, 2011

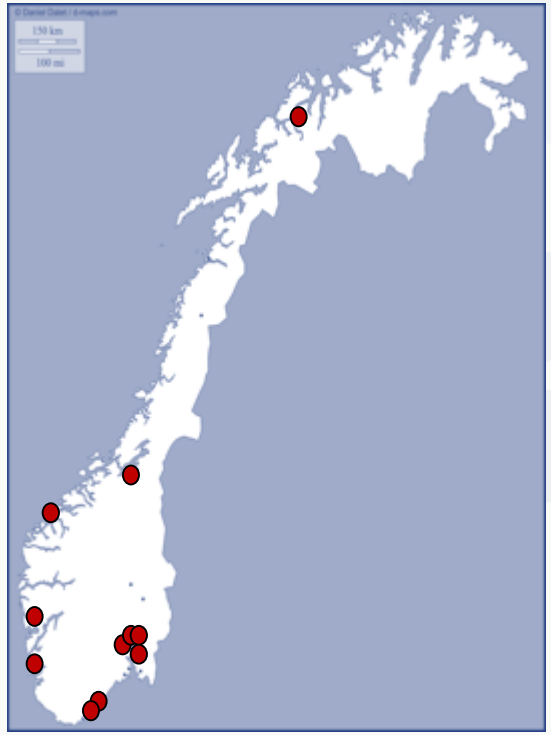
ARCTIC-studien

- Aiming for Remission in rheumatoid arthritis: a randomised trial examining the benefit of ultrasonography in a Clinical TIght Control regimen[1]
  - N=230
  - Inklusjon 2010-2013
- Pasientert randomisert til en av to behandlingsstrategier:
  - Målstyre behandlingen med ultralydinformasjon
  - Målstyre behandling basert på konvensjonelle sykdomsaktivitetsmål
- Strategistudie = sammenligner to behandlingsstrategier, ikke to medikamenter

Ref: Haavardsholm EA et al, The BMJ, 2015

ARCTIC studiegruppe

Local PIs	Study center
Hallvard Fremstad MD	Ålesund Hospital
Tor Magne Madland MD PhD	Haukeland University Hospital
Åse Stavland Lexberg MD	Vestre Viken Hospital Drammen
Hilde Haukeland MD	Martina Hansens Hospital
Erik Rødevand MD	St. Olavs Hospital Trondheim University Hospital
Christian Høili MD	Østfold Hospital Moss
Hilde Stray MD	Haugesund Sanitetsforening Rheumatism Hospital
Anne Noraas Bendvold MD	Specialist practice Bendvold/Dovland Kristiandsand
Inger Johanne Hansen MD	Sørlandet Hospital Kristiansand
Gunnstein Bakland MD PhD	University Hospital of Northern Norway Tromsø
Espen A. Haavardsholm MD PhD	Diakonhjemmet Hospital (coordinating center)



Diakonhjemmet Hospital

REMEDY

ARCTIC-studien

RESEARCH

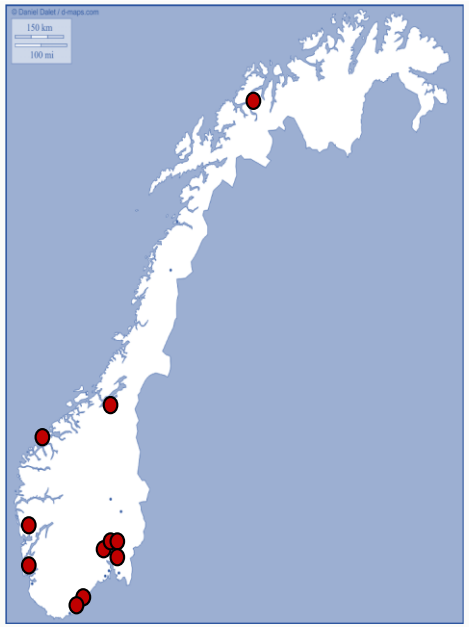
OPEN ACCESS

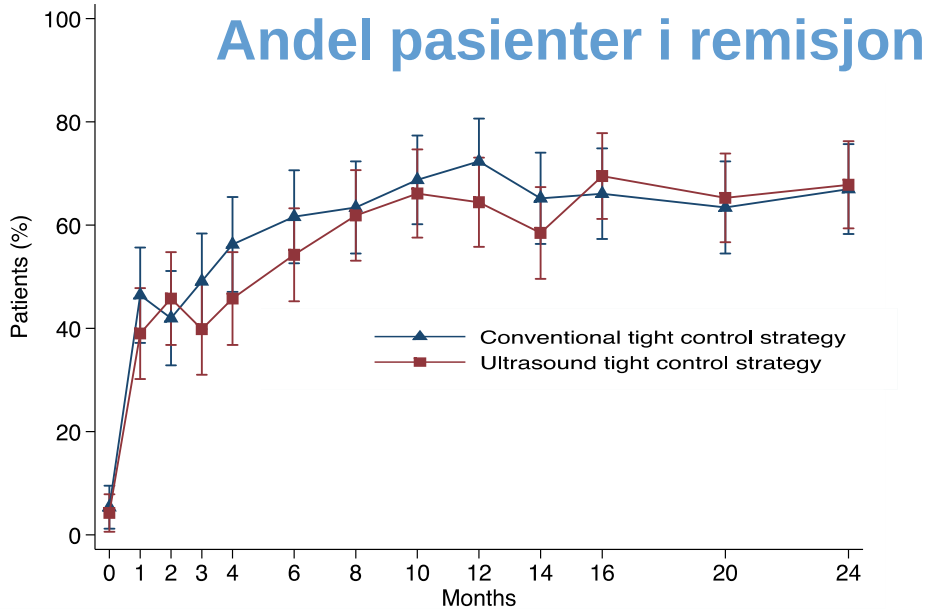
Ultrasound in management of rheumatoid arthritis: ARCTIC randomised controlled strategy trial

Espen A Haavardsholm,[1] Anna-Birgitte Aga,[1] Inge Christoffer Olsen,[1] Siri Lillegraven,[1] Hilde B Hammer,[1] Till Uhlig,[1] Hallvard Fremstad,[2] Tor Magne Madland,[3] Åse Stavland Lexberg,[4] Hilde Haukeland,[5] Erik Rødevand,[6] Christian Høili,[7] Hilde Stray,[8] Anne Noraas,[9] Inger Johanne Widding Hansen,[10] Gunnstein Bakland,[11,12] Lena Bugge Nordberg,[1] Désirée van der Heijde,[1,13] Tore K Kvien[1]

thebmj | *BMJ* 2016;354:i4205 | doi: 10.1136/bmj.i4205

Erfaringer fra gjennomført klinisk studie





Diakonhjemmet Hospital

REMEDY

Konklusjoner

- Tilsvarende resultater med konvensjonell oppfølging vs. ultralydoppfølging
- Negativ studie – men like viktig
- Illustrerer behovet for studier før innføring av nye behandlingsstrategier og undersøkelsesmetoder, ikke bare medikamenter

Forskerinitierte studier

ARCTIC THE ARCTIC TRIAL	Randomized clinical trial in early rheumatoid arthritis assessing management with and without ultrasound	thebmj
NOR SWITCH	Randomized clinical trial of switch from innovator infliximab to biosimilar infliximab	THE LANCET
NORD-STAR	Nordic randomized clinical trial in early rheumatoid arthritis comparing conventional therapy versus three biologic treatments	thebmj
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NOR DRUM The Norwegian drug monitoring study	Randomized clinical trial assessing the effectiveness of targeting infliximab treatment by therapeutic drug monitoring versus routine care	JAMA

Eksempel Ide 2: Kan vi bytte til biotilsvarende legemidler?

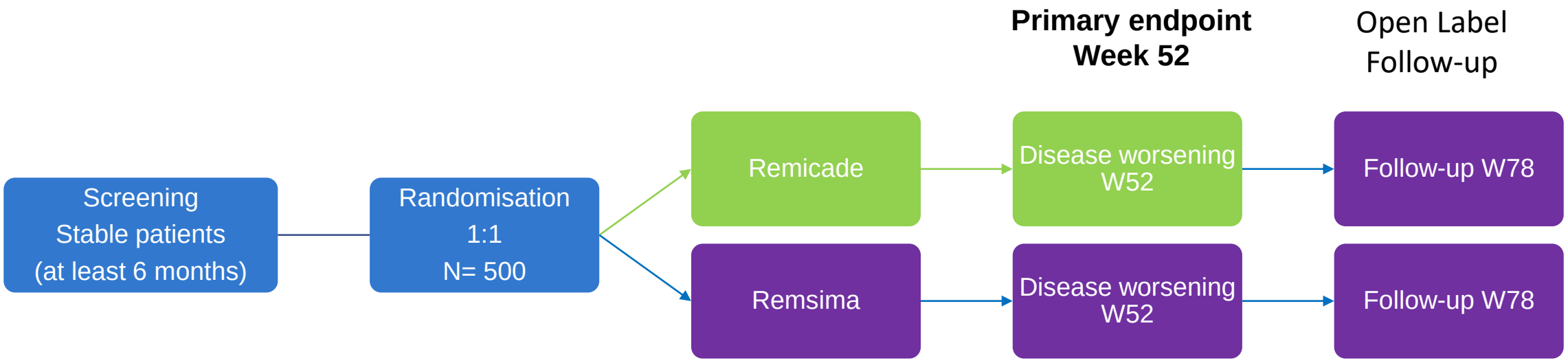
- 2015: Patentet utløper på infliximab og biotilsvarende infliximab blir tilgjengelig
- Biotilsvarende:
  - Lignende det originale produktet
    - Ikke bedre
    - Ikke verre
  - Billigere
  - Kan gi økt tilgang på effektiv behandling for pasienter med immunmedierte inflammatoriske sykdommer

Hovedmål

- Å undersøke om CT-P13 var non-inferior (ikke underlegen) sammenlignet med original infliximab (INX) med tanke på sykdomsforverring hos pasienter som har vært behandlet med stabil INX behandling i minst 6 måneder

- Sekundærmål:
  - Safety
  - Immunogenisitet

NOR- SWITCH Study design



Primary endpoint: Disease worsening
Non-inferiority margin:15%

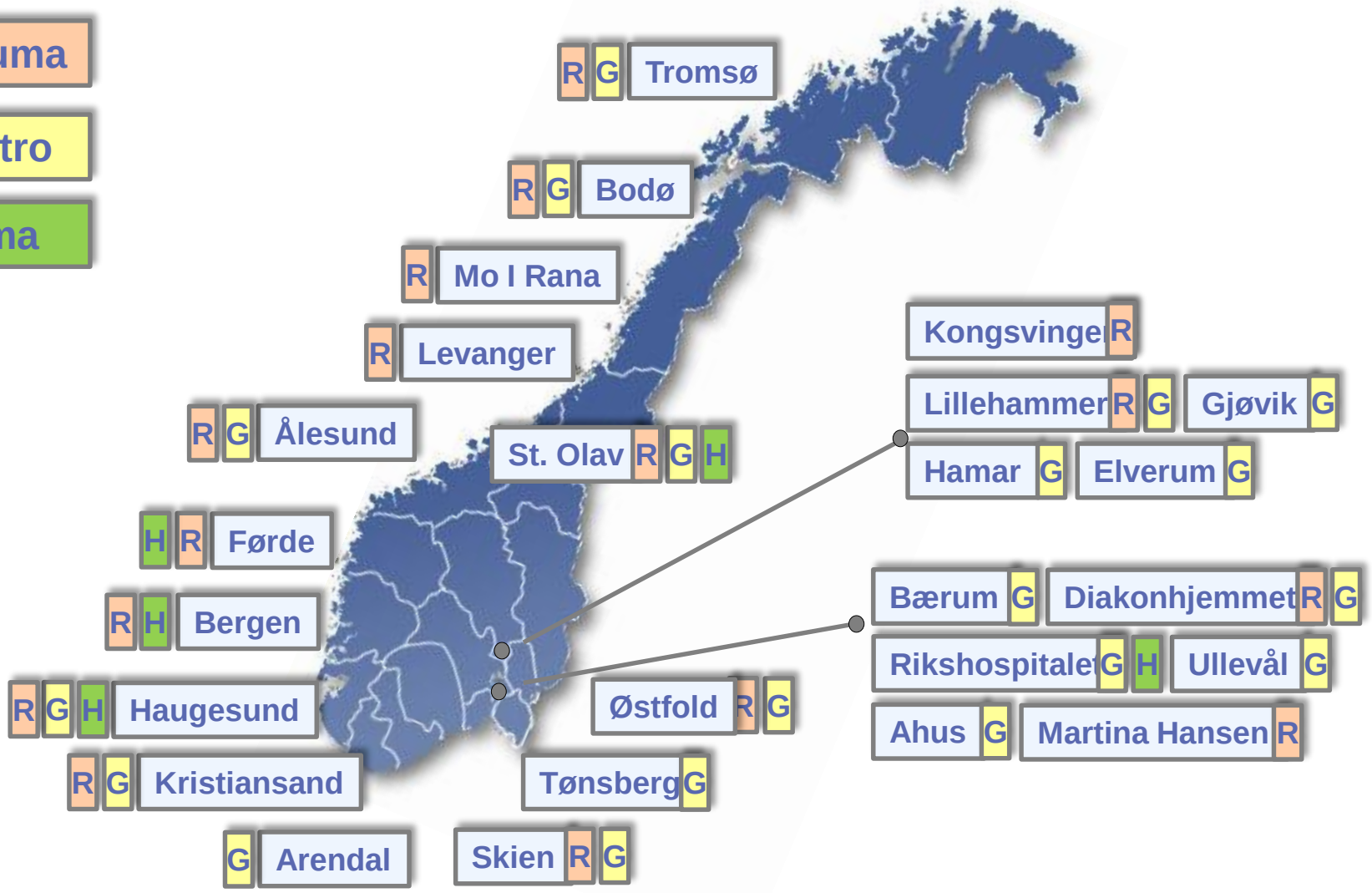
NOR SWITCH

Studiesentre

16 Rheuma

19 Gastro

5 Derma



Resultater: Sykdomsforverring

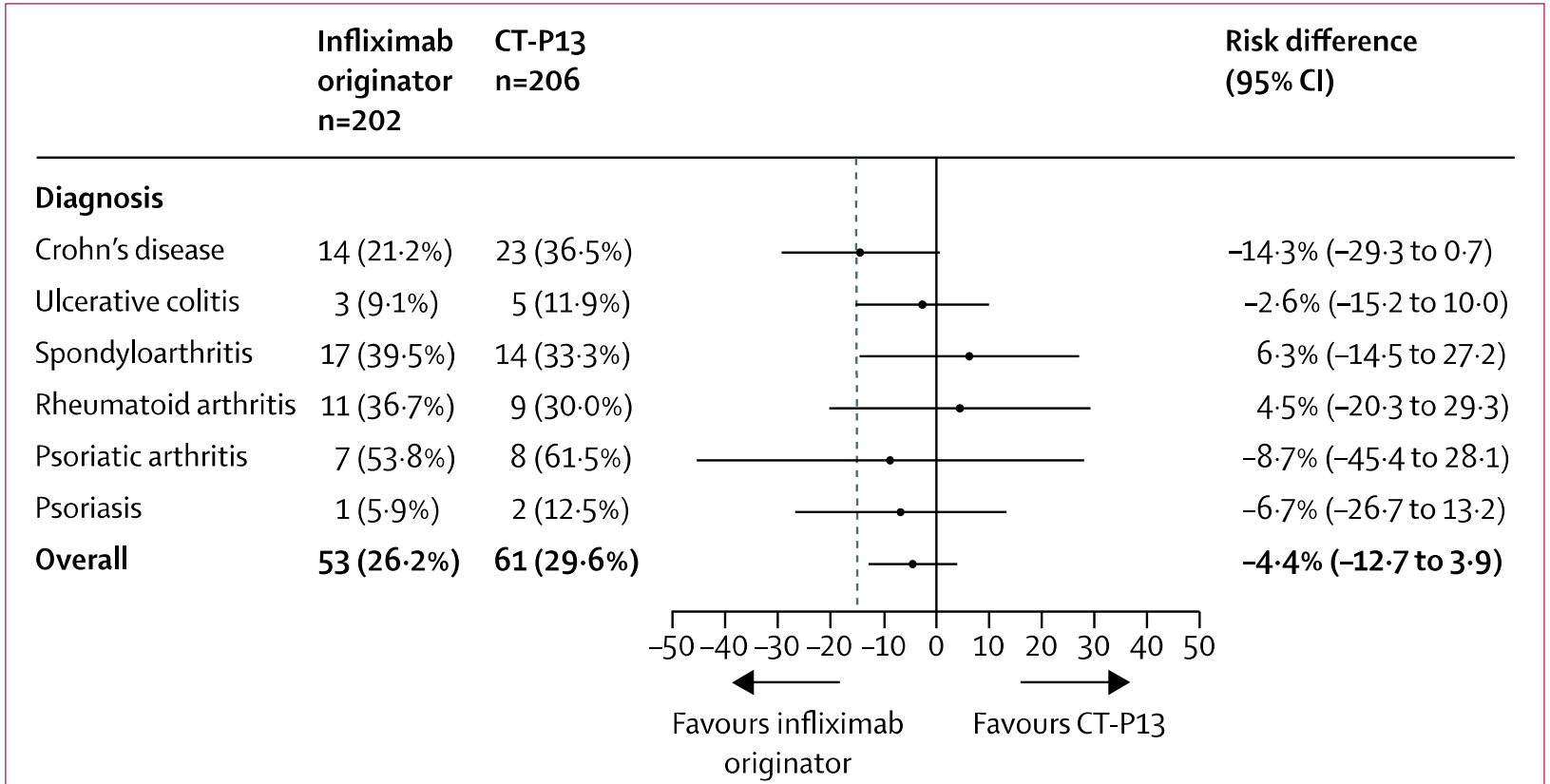
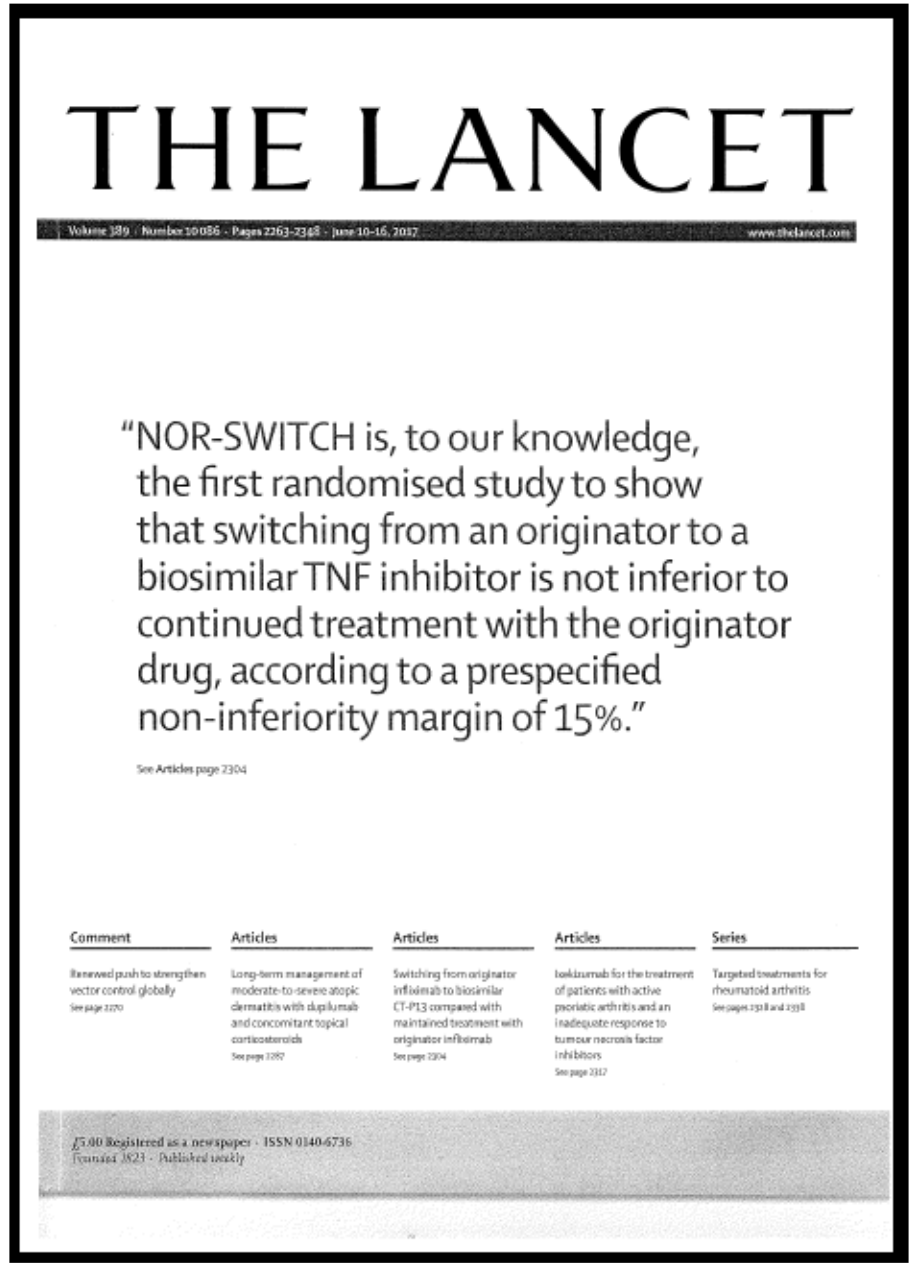


Figure 2: **Forest plot of risk difference according to disease**
Figure shows data for the per-protocol set. Risk difference is adjusted for treatment duration of infliximab originator at baseline.

Diakonhjemmet Hospital

Ref: Jørgensen KK et al, Lancet, 2017

NOR SWITCH DY


THE LANCET
Volume 389 · Number 10086 · Pages 2263–2348 · June 10–16, 2017
www.thelancet.com
"NOR-SWITCH is, to our knowledge, the first randomised study to show that switching from an originator to a biosimilar TNF inhibitor is not inferior to continued treatment with the originator drug, according to a prespecified non-inferiority margin of 15%."
See Articles page 2304
Comment
Renewed push to strengthen vector control globally
See page 2270
Articles
Long-term management of moderate-to-severe atopic dermatitis with dupilumab and concomitant topical corticosteroids
See page 2287
Articles
Switching from originator infliximab to biosimilar CT-P13 compared with maintained treatment with originator infliximab
See page 2304
Articles
Ixekizumab for the treatment of patients with active psoriatic arthritis and an inadequate response to tumour necrosis factor inhibitors
See page 2317
Series
Targeted treatments for rheumatoid arthritis
See pages 2328 and 2338
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Founded 1823 · Published weekly

Tolkning NOR-SWITCH

- Bytte fra orginal infliximab til biotilsvarende infliximab var ikke underlegent sammenlignet med fortsatt orginal infliximabbehandling

- Resultatene støtter bytte fra orginal infliximab til biotisvarende infliximab på ikke-medisinsk indikasjon

Banebrytende norsk studie åpner for viktige kopimedisiner

Biologiske medisiner har revolusjonert revmatiske sykdommer som leddgikt og tarmsykdommer som Chrons og Ulcerøs kolitt. Medisinene er svært kostbare, men en ny norsk studie åpner for langt billigere kopimedisiner.

Foto: Ola Mjaaland

Ola Mjaaland
@olamjaaland
Journalist

Publisert 12. mai 2017 kl. 21:34

Artikkelen er mer enn to år gammel.

NOR SWITCH

DAGENS Medisin — Nyheter Debatt DM Arena DMTV

VARSOM MED GENERALISERING – Etter vårt skjønn må vi være forsiktige med å generalisere bl.a. andre biologiske legemidler og deres biotilsvarende, sier Tore K. Kvien ved Diakonhjemmet sykehus. Han presenterer resultatene på gastroenterologisk kongress i Wien tirsdag 18. oktober. Arkivfoto: Vidar Sandnes

RESULTATENE KLARE FRA DEN NORSKE BYTTESTUDIEN

– Trygt å bytte til biotilsvarende

Verden over har ventet i spenning på resultatene fra Nor-Switch, som nå viser at det ikke er forskjell på Remicade og biotilsvarende. – Byttestudien gir tre streker under svaret, sier leder av studien, Tore K. Kvien.

Publisert: 2016-10-17 01:23
Lisbeth Nilsen

DAGENS Medisin — Nyheter Debatt DM Arena DMTV

– Nordmenn har grunn til å være stolte

Den tyske gastroenterologen Stefan Schreiber berømmer de norske forskerne. Han føler seg trygg på å bytte slik det er gjort i Nor-Switch-studien, men vil ha mer data på bytte med andre biotilsvarende.

Publisert: 2016-10-18 11:03 Skrevet av: Lisbeth Nilsen/Lasse Moe

DAGENS Medisin — Nyheter Debatt DM Arena DMTV

Britisk ekspert: – Nor-Switch er et vendepunkt

– Nor-Switch-studien vil øke bruken av biotilsvarende, og gir oss den real world evidence vi trenger, mener den britiske rådgiveren Michael Sobanja.

Publisert: 2016-10-18 09:40 Skrevet av: Lisbeth Nilsen/Lasse Moe
redaksjonen@dagensmedisin.no

DAGENS Medisin — Nyheter Debatt DM Arena DMTV

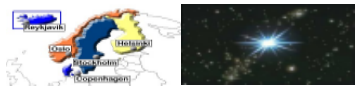
Blogger | Debatt og kronikk | Leder

– Vi trenger mer dokumentasjon enn én studie

Legemiddelindustrien (LMI) er positive til studier som kan føre til store besparelser for samfunnet. De peker på at det må gjøres flere studier som Nor-Switch for å skaffe mer kunnskap om biotilsvarende legemidler.

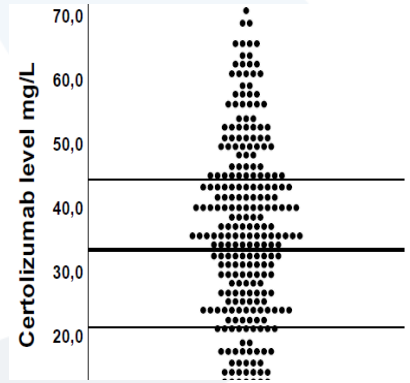
Publisert: 2016-10-17 12:18 Skrevet av: Lasse Moe

Forskerinitierte studier

ARCTIC THE ARCTIC TRIAL	Randomized clinical trial in early rheumatoid arthritis assessing management with and without ultrasound	thebmj
NOR SWITCH	Randomized clinical trial of switch from innovator infliximab to biosimilar infliximab	THE LANCET
 NORD-STAR	Nordic randomized clinical trial in early rheumatoid arthritis comparing conventional therapy versus three biologic treatments	thebmj
ARCTIC REWIND	Randomized clinical trial in rheumatoid arthritis assessing withdrawal of disease-modifying drugs	JAMA
NOR DRUM The Norwegian drug monitoring study	Randomized clinical trial assessing the effectiveness of targeting infliximab treatment by therapeutic drug monitoring versus routine care	JAMA

Ide eksempel 3:
Gir terapeutisk legemiddel monitorering (TDM) bedre effekt av TNFα-hemmere?

- Variabilitet i serumnivå av TNF α
- Assosiasjon mellom serum nivå og klinisk respons
- Terapeutisk legemiddel monitorering:



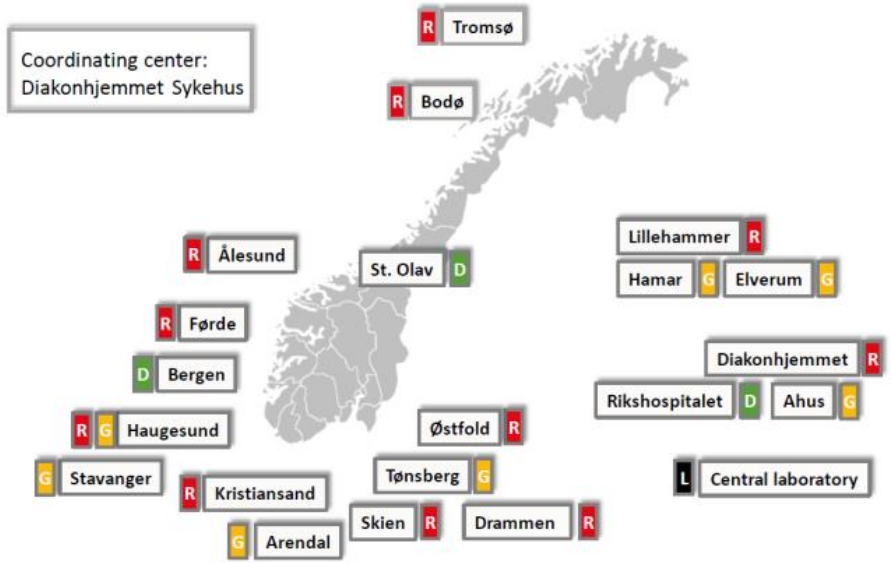
Gehin et al. ART 2019

Holde serumnivået i terapeutisk vindu
Oppdage anti-legemiddel antistoffer
Forebygge behandlingssvikt
Unngå overdosering

Formål

Undersøke om TDM gir økt effekt av infliximab

- Induksjons perioden (NOR-DRUM A)
- Vedlikeholdsperioden (NOR-DRUM B)



Diakonhjemmet Hospital

NOR DRUM The Norwegian drug monitoring study

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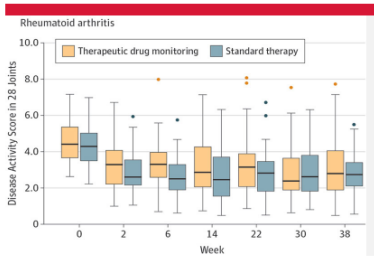

Effect of Therapeutic Drug Monitoring vs Standard Infliximab Induction on Chronic Immune-Mediated Inflammatory Disease Remission

Effect of Half- vs Stable-Dose Conventional Synthetic DMARDs on Disease Flares in Patients With RA in Remission

Editorial: Treatment Strategies for Immune-Mediated Inflammatory Diseases

Just Published May 5, 2021

JAMA | Original Investigation

Effect of Therapeutic Drug Monitoring vs Standard Therapy During Infliximab Induction on Disease Remission in Patients With Chronic Immune-Mediated Inflammatory Diseases

A Randomized Clinical Trial

Silje Watterdal Syversen, MD, PhD; Guro Løvik Goll, MD, PhD; Kristin Kaasen Jørgensen, MD, PhD; Øystein Sandanger, MD, PhD; Joseph Sexton, PhD; Inge Christoffer Olsen, PhD; Johanna Elin Gehin, MD; David John Warren, PhD; Marthe Kirkesæther Brun, MD; Rolf Anton Klaasen, PhD; Lars Normann Karlsen, MD; Geir Noraberg, MD; Camilla Zettel, MD; Maud Kristine Aga Ljoså, MD; Anne Julsrud Haugen, MD, PhD; Rune Johan Njålla, MD; Trude Jannecke Bruun, MD; Kathrine Aglen Seeberg, MD; Brigitte Michelsen, MD, PhD; Eldri Kveine Strand, MD; Svanaug Skorpe, MD; Ingrid Marianne Blomgren, MD; Yngvill Hovde Bragnes, MD; Christian Kvikne Dotterud, MD, PhD; Turid Thune, MD; Carl Magnus Ystrøm, MD; Roald Torp, MD; Pawel Mielnik, MD, PhD; Cato Mørk, MD, PhD; Tore K. Kvien, MD, PhD; Jørgen Jahnsen, MD, PhD; Nils Bolstad, MD, PhD; Espen A. Haavardsholm, MD, PhD

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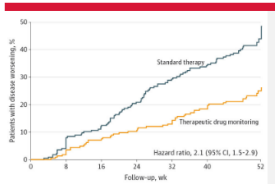

Effect of Therapeutic Drug Monitoring vs Standard Therapy During Maintenance Infliximab Therapy in Patients With Immune-Mediated Inflammatory Diseases (IMID): An RCT

Editorial: Therapeutic Drug Monitoring for IMID

December 21, 2021

CME

Just Published December 21, 2021

Research

Therapeutic Drug Monitoring During Maintenance Infliximab Therapy for Immune-Mediated Diseases

Silje Watterdal Syversen, MD, PhD; et al.

Original Investigation

CME

Editorial

Opinion

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Amanda C. Cohn, MD; et al.

Viewpoint

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Maroun M. Sfeir, MD, MPH, MS; et al.

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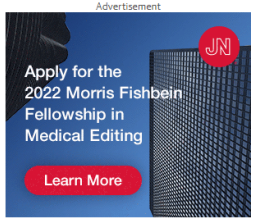

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Research

JAMA | Original Investigation

Effect of Therapeutic Drug Monitoring vs Standard Therapy During Maintenance Infliximab Therapy on Disease Control in Patients With Immune-Mediated Inflammatory Diseases

A Randomized Clinical Trial

Silje Watterdal Syversen, MD, PhD; Kristin Kaasen Jørgensen, MD, PhD; Guro Løvik Goll, MD, PhD; Marthe Kirkesæther Brun, MD; Øystein Sandanger, MD, PhD; Kristin Hammersbøen Bjørlykke, MD; Joseph Sexton, PhD; Inge Christoffer Olsen, PhD; Johanna Elin Gehin, MD; David John Warren, PhD; Rolf Anton Klaasen, PhD; Geir Noraberg, MD; Trude Jannecke Bruun, MD; Christian Kvikne Dotterud, MD, PhD; Maud Kristine Aga Ljoså, MD; Anne Julsrud Haugen, MD, PhD; Rune Johan Njålla, MD; Camilla Zettel, MD; Carl Magnus Ystrøm, MD; Yngvill Hovde Bragnes, MD; Svanaug Skorpe, MD; Turid Thune, MD; Kathrine Aglen Seeberg, MD; Brigitte Michelse Ingrid Marianne Blomgren, MD; Eldri Kveine Strand, MD; Pawel Mielnik, MD, PhD; Roald Torp, MD; Cato Mørk, MD, Tore K. Kvien, MD, PhD; Jørgen Jahnsen, MD, PhD; Nils Bolstad, MD, PhD; Espen A. Haavardsholm, MD, PhD

NOR DRUM

JAMA Network™

QUESTION Among patients with chronic immune-mediated inflammatory diseases initiating treatment with infliximab, does proactive therapeutic drug monitoring improve clinical remission rates compared with standard therapy?

CONCLUSION Proactive therapeutic drug monitoring, compared with standard therapy, did not significantly improve clinical remission rates over 30 weeks among patients with immune-mediated inflammatory diseases initiating treatment with infliximab.

POPULATION

202 Men
209 Women

Adults with rheumatoid arthritis, spondyloarthritis, psoriatic arthritis, ulcerative colitis, Crohn disease, or psoriasis initiating infliximab therapy

Mean age: **45** years

LOCATIONS

21 Hospitals in Norway

INTERVENTION

411 Patients randomized
398 Patients analyzed

198
Therapeutic drug monitoring
Dose and interval adjustments based on scheduled monitoring of serum drug levels and antidrug antibodies

200
Standard therapy
Standard infliximab therapy without drug and antibody level monitoring

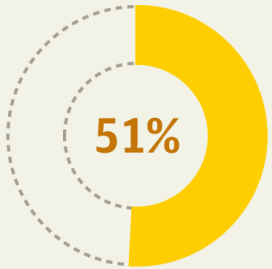
PRIMARY OUTCOME

Clinical remission at week 30, defined by disease-specific assessment composite scores

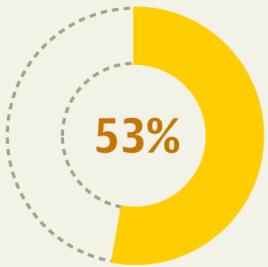
FINDINGS

Clinical remission at week 30

Therapeutic drug monitoring
100 of 198 patients



Standard therapy
106 of 200 patients



The adjusted between-group difference was not significant:

1.5% (95% CI, −8.2% to 11.1%); *P* = .78

© AMA

Syversen SW, Goll GL, Jørgensen KK, et al. Effect of therapeutic drug monitoring vs standard therapy during infliximab induction on disease remission in patients with chronic immune-mediated inflammatory diseases: a randomized clinical trial. *JAMA*. Published May 4, 2021. doi:10.1001/jama.2021.4172

Diakonhjemmet Hospital

NOR DRUM The Norwegian drug monitoring study

REMEDY

JAMA Network™

QUESTION Among patients with immune-mediated inflammatory diseases undergoing maintenance therapy with infliximab, is proactive therapeutic drug monitoring more effective than standard therapy to sustain disease control without disease worsening?

CONCLUSION Proactive therapeutic drug monitoring was more effective than standard therapy in sustaining disease control without disease worsening among patients with immune-mediated inflammatory diseases undergoing maintenance therapy with infliximab.

POPULATION

238 Men
216 Women

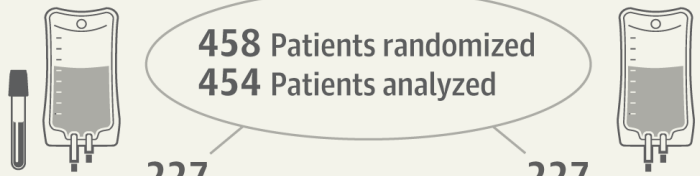
Adults with rheumatoid arthritis, spondyloarthritis, psoriatic arthritis, ulcerative colitis, Crohn disease, or psoriasis undergoing infliximab maintenance therapy

Mean age: 45 years

LOCATIONS

20 Hospitals in Norway

INTERVENTION



Therapeutic drug monitoring

Dose and interval adjustments based on scheduled monitoring of serum drug levels and antidrug antibodies

Standard therapy

Standard infliximab therapy without drug and antibody level monitoring

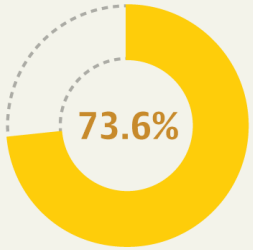
PRIMARY OUTCOME

Sustained disease control without disease worsening over 52 weeks, defined by disease-specific composite scores or patient-physician consensus on disease worsening leading to a major change in treatment

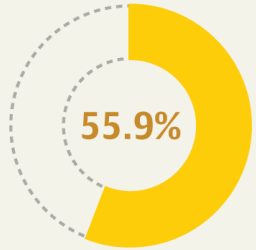
FINDINGS

52-Week sustained disease control

Therapeutic drug monitoring
167 of 227 patients



Standard therapy
127 of 227 patients



The adjusted between-group difference was significant:

17.6% (95% CI, 9.0%-26.2%); *P* < .001

© AMA

Syversen SW, Jørgensen KK, Goll GL, et al. Effect of therapeutic drug monitoring vs standard therapy during maintenance infliximab therapy on disease control in patients with immune-mediated inflammatory diseases: a randomized clinical trial. *JAMA*. Published December 21, 2021. doi:10.1001/jama.2021.21316

Diakonhjemmet Hospital

NOR DRUM The Norwegian drug monitoring study

REMEDY

Medscape

News > Medscape Medical News

Proactive Infliximab Monitoring Found Best for Sustaining Control of Inflammatory Diseases

Steve Cimino

December 21, 2021

A new study has found that proactive therapeutic drug monitoring (TDM) with maintenance infliximab is more effective than standard therapy in sustaining control of immune-mediated inflammatory diseases.

The findings from the trial, published December 21 in JAMA, called Norwegian Drug Monitoring B (NOR-DRUM B), provide greater support to the usefulness of TDM in proactively monitoring serum drug levels and antidrug antibodies to infliximab, which has been previously shown to have benefit in patients with inflammatory bowel disease, but leave the benefits of proactive vs reactive

DAGENS Medisin Nyheter Debatt Pharma DM Arena

Vekker oppsikt med publisering: Forskerne tok en dobbel JAMA

Diakonhjemmet Hospital

DAGENS Medisin Nyheter Debatt Pharma DM Arena

Skryter av Diakonhjemmets innsats

Også Magne Nylenna, lege og fagdirektør ved FHI, trekker frem at sykehuset har fått dette til, selv om de er et mindre sykehus, og et ikke-universitetssykehus.

– Altså, her må jeg skryte, selv om jeg jo litt inhabil siden jeg er tidligere styremedlem ved sykehuset, men; det er helt eksepsjonelt at et såpass lite sykehus får frem et så godt forskermiljø.

– To slike artikler i JAMA kommer ikke ut ved en tilfeldighet. Ved dette sykehuset er det gitt rom til forskning. Det skal de ha veldig kred for. Sist jeg sjekket, viste listen over publiseringsaktivitet i Norge at Diakonhjemet er det klart største etter universitetssykehusene, sier Nylenna.

Sjefredaktøren i Tidsskrift for Den norske legeforening, Are Brean, har følgende å si om «JAMA-dobbelen»:

– JAMA er et høyt renommert tidsskrift, og det er imponerende å få publisert begge studiene der. Dette ser ut som to meget solide gjennomførte studier, rent metodologisk. Og – de ser ut til å være godt gjennomført når det kommer til logistikk, som ofte er utfordrende å få til i såpass store kliniske studier.

– Her ser vi også nytten av at kliniske avdelinger ved flere sykehus samarbeider om pasientnær klinisk forskning. I tillegg er det veldig artig at forskningen springer ut fra et ikke-universitetssykehus. Dette viser viktigheten av at vi har finansieringsordninger også for gode klinikerinitierte, pasientnære studier.

DAGENS Medisin

Studie: Fikk bedre sykdomskontroll ved å overvåke blodnivå

En ny publikasjon i prestisjetidsskriftet JAMA viser effekt av å benytte regelmessige målinger av legemiddelkonsentrasjon i blodet som utgangspunkt for behandlingen av pasienter med immunologiske sykdommer.

NY BRAGD: Forskerne bak NOR-DRUM-studien ble avbildet i sommer i forbindelse med den første JAMA-publiseringen.

NOR DRUM

REMEDY

Oppsummering - eksempler

- Viktig at begge utfall av studien er av interesse
- Studier som svarer på kliniske spørsmål → innvirkning på klinisk praksis
- Gjennomføring av studier er krevende, krever årelang innsats og betydelig finansiering
  - Men er mulig på ikke-universitetssykehus!

Innhold

- Eksempler – fra ide til protokoll
- Problemstilling
  - Klinisk relevans
  - Pasientgrunnlag
  - Nytteverdi
- Praktisk ved prosjektstart
  - Forankring i sykehuset og i klinisk drift
  - Ressurser (personale, tid)
  - Forfatterskap/vitenskapelig samarbeid
- Prosjektskisse

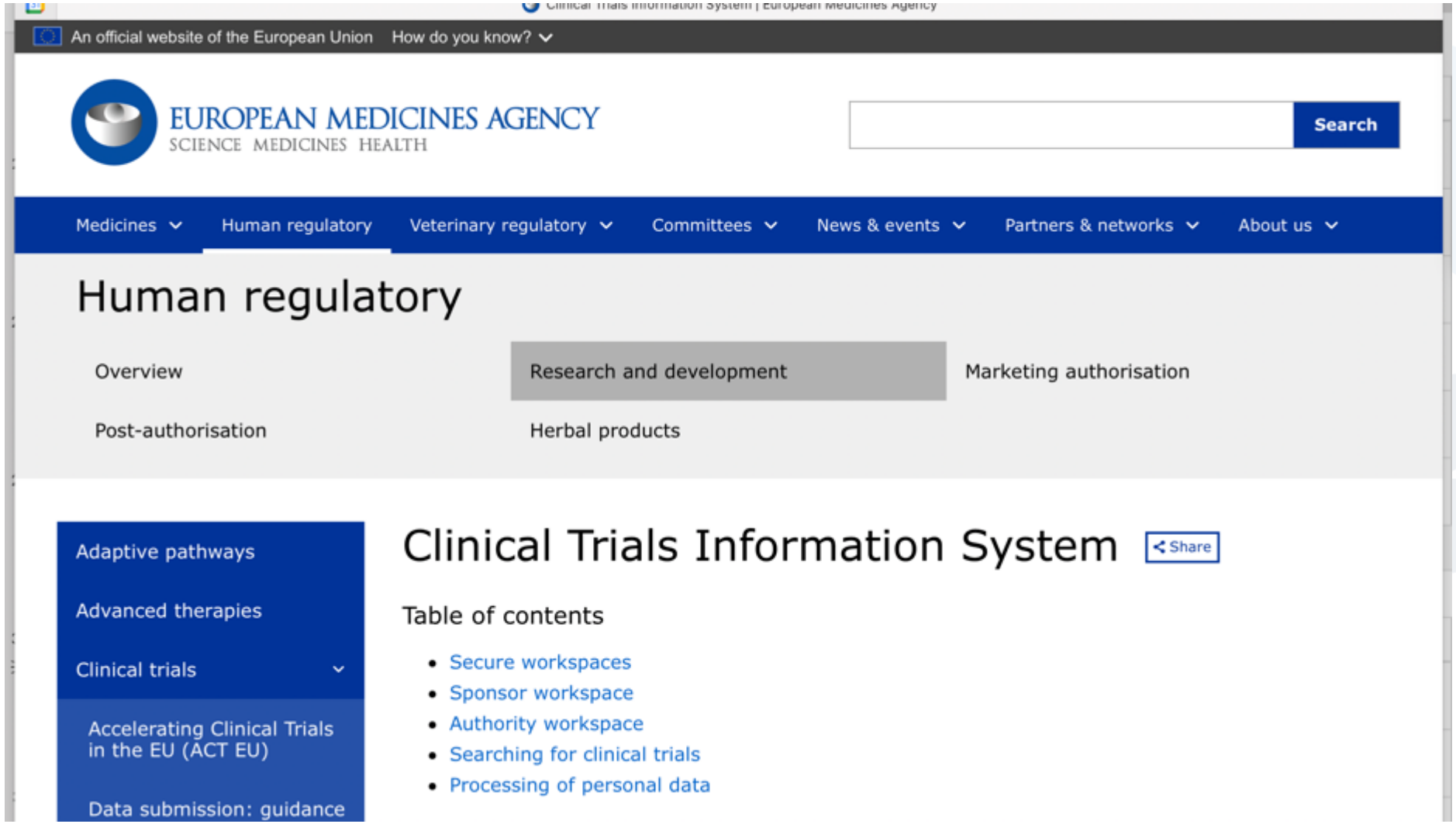
Forskningsspørsmål

- Forskningsspørsmålet bør/skal besvare en viktig problemstilling og påvirke klinisk praksis

- Forskningsspørsmålet bør være så viktig at du ikke er i tvil om:
  - At du bør få innvilget støtte
  - At du vil bruke mange av dine (beste?) år i arbeidslivet på studien

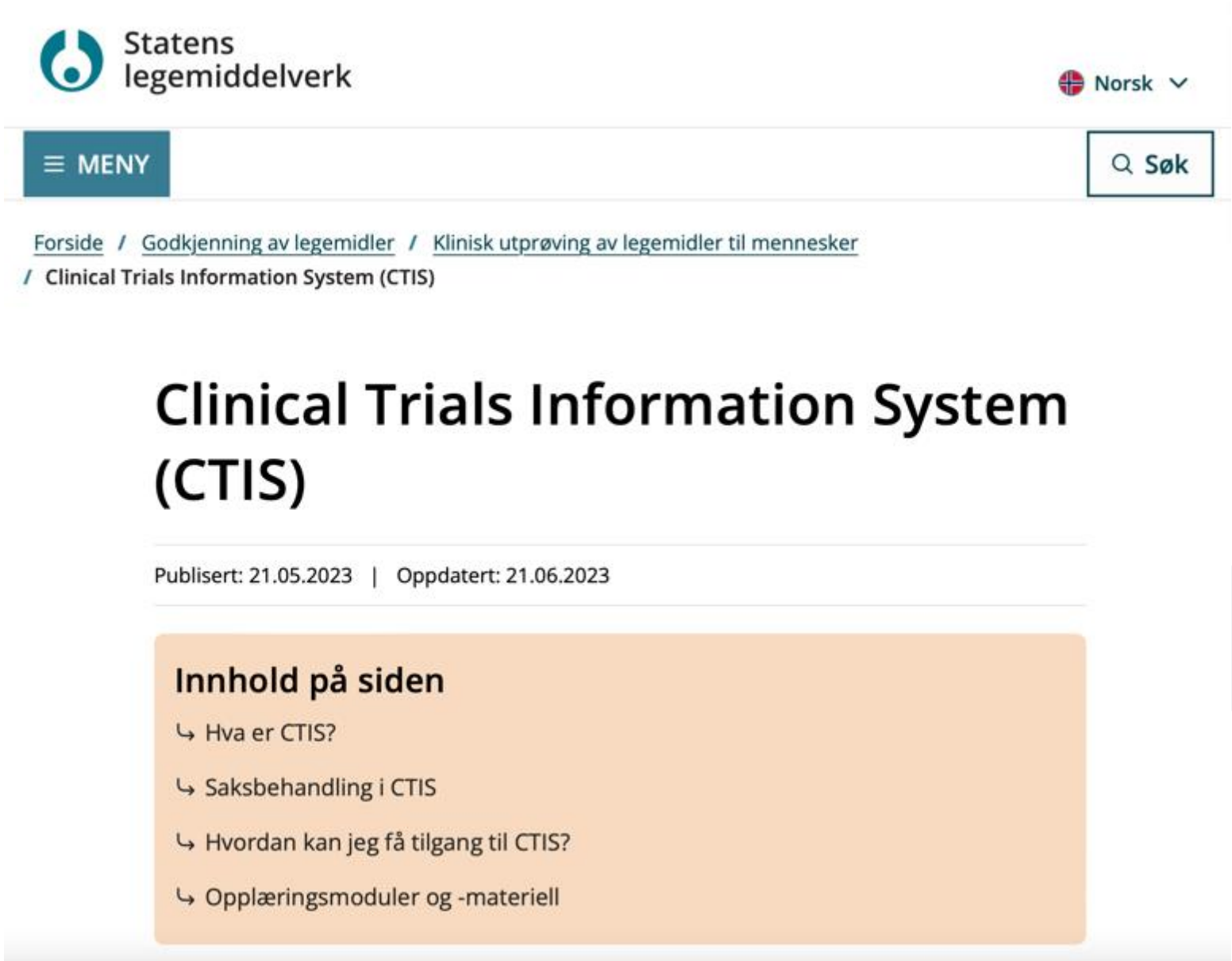
- Hvis du er i tvil, vanskeligere å overbevise andre

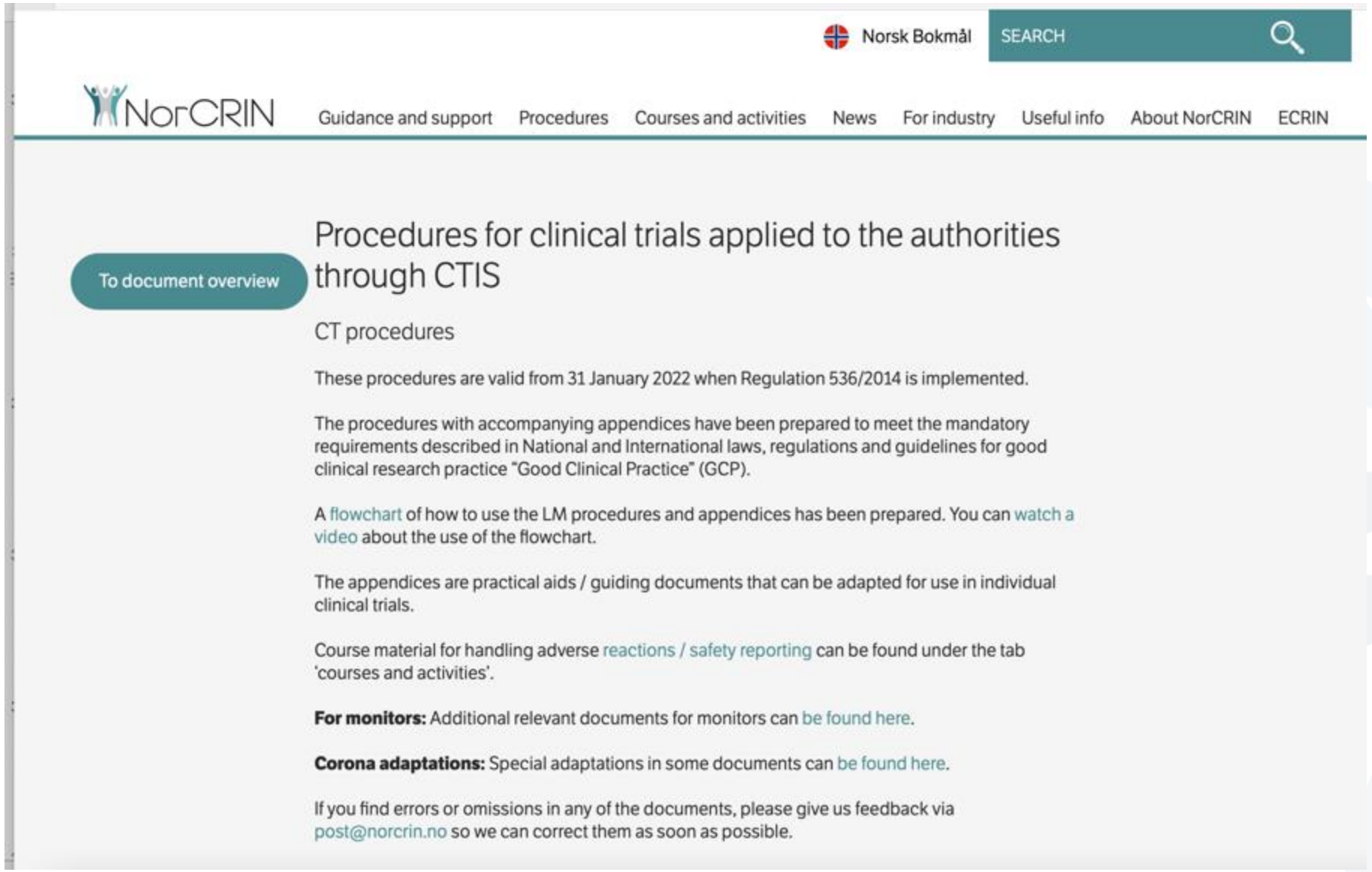
VIKTIG AVKLARING!! Søknadspliktig CTIS?



Diakonhjemmet Hospital

REMEDY


Statens legemiddelverk
Norsk
MENY
Søk
Forside / Godkjenning av legemidler / Klinisk utprøving av legemidler til mennesker / Clinical Trials Information System (CTIS)
Clinical Trials Information System (CTIS)
Publisert: 21.05.2023 | Oppdatert: 21.06.2023
Innhold på siden
Hva er CTIS?
Saksbehandling i CTIS
Hvordan kan jeg få tilgang til CTIS?
Opplæringsmoduler og -materiell


Norsk Bokmål
SEARCH
NorCRIN
Guidance and support
Procedures
Courses and activities
News
For industry
Useful info
About NorCRIN
ECRIN
To document overview
Procedures for clinical trials applied to the authorities through CTIS
CT procedures
These procedures are valid from 31 January 2022 when Regulation 536/2014 is implemented.
The procedures with accompanying appendices have been prepared to meet the mandatory requirements described in National and International laws, regulations and guidelines for good clinical research practice "Good Clinical Practice" (GCP).
A flowchart of how to use the LM procedures and appendices has been prepared. You can watch a video about the use of the flowchart.
The appendices are practical aids / guiding documents that can be adapted for use in individual clinical trials.
Course material for handling adverse reactions / safety reporting can be found under the tab 'courses and activities'.
For monitors: Additional relevant documents for monitors can be found here.
Corona adaptations: Special adaptations in some documents can be found here.
If you find errors or omissions in any of the documents, please give us feedback via post@norcrin.no so we can correct them as soon as possible.

Pasientgrunnlag

- Inklusjons- og eksklusjonskriterier
- Eksisterer disse pasientene?
- VIKTIG! Avgjørende del av studieplanleggingen

Tidslinje

- **Tidlig fase**
  - Definere forskningsspørsmål/hypotese
  - Synopsis
  - Finansiering
- **Studie besluttet igangsatt**
  - Utvikle protokoll
  - Regional etisk komite / Statens legemiddelverk

1-2 år

- **Aktiv fase**
  - Pasientinklusjon
  - Datainnsamling
  - Datasjekker

1-5 år

- **Resultater**
  - Koding
  - Analyser inkl. analyseplan
  - Publisering

6-12 mnd.

- **Forlengelse, publisering sekundære mål**

REMEDY

- **Tidlig fase**
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  - Koding
  - Analyser inkl. analyseplan
  - Publisering

6-12 mnd.

- **Forlengelse, publisering sekundære mål**

Inklusjon 1. pasient

KLINBEFORSK

Nasjonal oppstart

Siste pasient inkludert A

Siste pasient fullført A

Siste pasient inkludert B

Siste pasient fullført B

Publikasjon NOR-DRUM A

Publikasjon NOR-DRUM B

2016 **2017** **2018** **2019** **2020** **2021**

JAMA JAMA JIM

Diakonhjemmet Hospital

REMEDY

Dedikasjon

- Kliniske studier er kompliserte!
- Krever betydelig dedikasjon og utholdenhet, særlig av hovedutprøver/prosjektleder
- Krever støtte fra koordinerende senter

Innhold

- Eksempler – fra ide til protokoll
- Problemstilling
  - Klinisk relevans
  - Pasientgrunnlag
  - Nytteverdi
- Praktisk ved prosjektstart
  - Forankring i sykehuset og i klinisk drift
  - Ressurser (personale, tid)
  - Forfatterskap/vitenskapelig samarbeid
- Prosjektskisse

Synopsis

PROTOCOL SYNOPSIS

TITLE	
Phase of development	
Investigational treatment strategy	
Study Centres	
Study organisation	
Study Period	
Duration	
Primary objective	
Secondary objectives	
Endpoints	
Study Design	
Main Inclusion Criteria	
Main exclusion criteria	
Sample size	
Hypothesis and statistical model	

Diakonhjemmet Hospital

REMEDY

Prosjektbeskrivelse

Modern treatment of rheumatoid arthritis

Applicant Siri Lillegraven, MD MPH PhD
Dept. of Rheumatology, Diakonhjemmet Hospital, Oslo

2) INTRODUCTION

This application for a career fellowship outlines five work packages (WPs) to improve modern treatment of rheumatoid arthritis (RA) (**figure 1**). The proposed work aims to increase the knowledge of how early RA and RA remission should be treated, considering both patients and society. The project uses data from three studies and includes the main analyses of the Norwegian multi-center randomized clinical trial ARCTIC REWIND, which assesses the effects of tapering and withdrawal of disease-modifying antirheumatic drugs (DMARDs) in sustained RA remission.

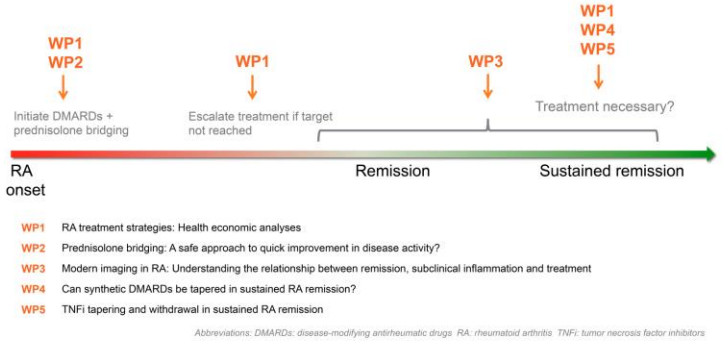


Figure 1: Conceptual illustration of the project

An introduction to RA

RA is a chronic inflammatory disease predominantly affecting women [3]. The main feature is joint inflammation with subsequent joint destruction, but the disease can also have extra-articular manifestations and be associated with increased risk of cardiovascular disease and reduced life-expectancy [4]. In early disease, disability is driven by disease activity, and thus reversible with successful medical treatment (**figure 2**). RA is treated with DMARDs, which are classified as synthetic (e.g. methotrexate, sulfasalazine), biologic (e.g. tumor necrosis factor inhibitors (TNFi), rituximab) [3, 5, 6] or targeted synthetic (e.g. janus kinase inhibitors) [3].

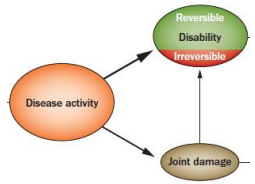


Figure 2: Disease activity, disability and joint damage in early RA [2]

Modern RA treatment and remission

The introduction of biologic DMARDs has changed the outcome of RA, and the goal in modern RA treatment has become to reach and sustain remission, with prevention of structural joint damage and disability [5, 6]. Synthetic DMARD treatment is started when a patient is diagnosed, with initial corticosteroid bridging according to current treatment recommendations [3, 5]. Although the use of corticosteroids when initiating synthetic DMARDs is supported by considerable evidence, the dosing, administration route and duration is debated and experts struggle to agree on a definite recommendation [5]. RA treatment strategies now implement tight control of RA care, with a

A **NOR**wegian randomized **S**trategy trial in **P**so**R**iatic arthritis: **I**magi**N**g **T**reat-to-target vs conventional treat-to-target

The NOR-SPRINT study

2) INTRODUCTION

Psoriatic arthritis (PsA) is a heterogeneous inflammatory disease which may affect several musculoskeletal structures and skin. Treatment should be tailored based on presentation in the individual patient as some of the potential drugs have limited or no effect on certain features. However, inflammatory involvement may be difficult to assess clinically in PsA. This application outlines a Norwegian multi-center study comparing a novel treatment strategy actively assessing the patient with modern imaging techniques to tailor the treatment based on imaging findings, to a conventional treatment strategy. The results will potentially make significant changes in the treatment of this patient group.

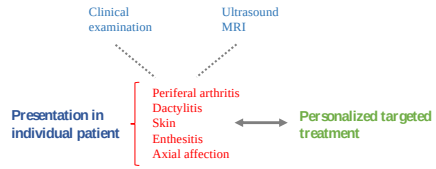


Figure 1: Conceptual illustration of the project

An introduction to psoriatic arthritis

PsA occurs in about 30% of psoriasis patients, and is characterized by diverse clinical features, often resulting in delayed diagnosis and treatment[1]. Disease manifestations include arthritis, tenosynovitis, enthesitis, axial inflammation, skin- and nail changes. Norwegian data have yielded prevalence estimates of 2.0 (Bergen) and 6.7 (Nord-Trøndelag) cases per 1000 inhabitants in the adult population[2,3]. Persistent disease activity will, in addition to the immediate symptoms of inflammation, result in joint damage in a significant proportion of patients[4,5] with associated permanent loss of function[5,6], reduced quality of life[7] and decreased work participation[8]. PsA is also associated with increased risk of cardiovascular disease[9].

Assessment of inflammation in psoriatic arthritis

All pharmacological treatments of PsA are targeted at reducing inflammation, thus the detection of inflammation is crucial to make appropriate treatment decisions. The overarching goal of PsA treatment is to ensure symptom control and prevention of structural damage, while avoiding unnecessary exposure to treatments with risk of adverse events. Because of the heterogeneous nature of PsA, it has been difficult to define how to best record disease activity at clinical visits. Current disease activity measures are based a combination of patient reported outcomes (PROs) and clinical assessment. Patients reported symptoms and functional assessments partially reflects inflammation, but is also influenced by factors that should not be treated by anti-inflammatory medication, such as established joint damage and comorbid conditions, including fibromyalgia and widespread pain syndromes. Clinical assessment of joints and entheses are core measures of disease activity, but there are concerns regarding both their validity and their reliability in a clinical setting[10].

Modern imaging techniques, such as ultrasound and magnetic resonance imaging (MRI), is widely used in rheumatology. Ultrasound can be a useful tool to examine joints, tendons and entheses[11] bedside, with direct visualization of subclinical inflammation such as by the finding of power Doppler activity. Subclinical ultrasound synovitis has been found in three of four newly diagnosed PsA patients[12] and subclinical inflammation of joints, tendons and entheses has also been detected in a large proportion of patients found to be in clinical remission[13]. MRI is the only reliable method to assess inflammation of the sacroiliac joints and the spine, and is an established part of axial spondyloarthritis classification criteria [14,15]. However, although axial affection is a feature of PsA, data on imaging of the columna in PsA are scarce and there is no consensus on to what extent it would be beneficial to perform axial MRIs routinely in this patient group[16].

Diakonhjemmet Hospital

1. PROJECT TITLE

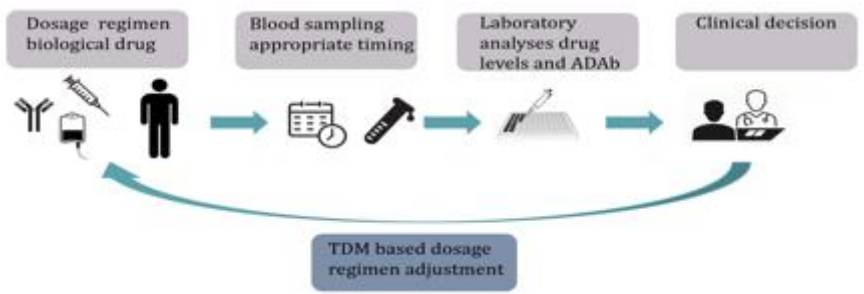
Assessing the efficacy of proactive therapeUtic dRug monitORing of Adalimumab therapy: The AURORA trial

2. INTRODUCTION

This application outlines the AURORA trial, a multicentre randomised controlled trial, aiming at optimising therapy with subcutaneous (SC) tumour necrosis factor alpha inhibitors (TNFi) in patients with immune- mediated inflammatory diseases (IMIDs). IMIDs such as inflammatory bowel- and joint diseases constitute a significant burden for the patient, health-care systems and society. The proposed study will assess whether a personalised treatment strategy based on therapeutic drug monitoring (TDM) improves efficacy of adalimumab therapy, the most frequently used TNFi both globally and nationally. The study will include patients with rheumatoid arthritis (RA), spondyloarthritis (SpA), ulcerative colitis (UC) or Crohn's disease (CD) on adalimumab therapy and is expected to provide clinically valuable information that will hopefully contribute to reduce the disease burden in these common chronic inflammatory diseases with a potentially disabling disease course, as well as a to reduce expenses related to biological therapy.

The steering group of this proposal consisting of major clinical rheumatological and gastroenterological centres within the Eastern Norway Regional Health Authority possesses the expertise, network and infrastructure necessary to fill current knowledge gaps within this field. The AURORA trial will build on the infrastructure, organisation and research collaboration already established for the successful NOR-SWITCH and NOR-DRUM studies[1-4], previous extensive efforts within Norwegian rheumatology and gastroenterology. As outlined in the budget, a recent EU grant (Horizon-HLTH-2022) to the project "Maximising Impact of Prescription Drugs in Rheumatoid Arthritis" with Diakonhjemmet Hospital and Oslo University Hospital as partners, has secured funding for operating costs and personnel related to the RA patients in the proposed study. The current grant proposal will enable AURORA as a multi-disciplinary study that includes patients both from gastroenterology and rheumatology. The experience with NOR-DRUM has highlighted the importance of multicentre, multi-disciplinary research collaborations within this field, and by the AURORA trial we hope to take further advantage of the rewarding research alliance between clinical rheumatology and gastroenterology and leading research communities within laboratory medicine, clinical immunology and genetics.

Development and implementation of personalised medicine in the healthcare services is a national and regional strategic research goal[5]. The impact of TDM of biological therapy is currently a topic of great interest to clinicians both nationally and internationally.



Personalised management of early inflammatory arthritis

APPLICANT

Silje Watterdal Syversen, MD PhD
Center for treatment of Rheumatic and Musculoskeletal Diseases (REMEDY)
Division of Rheumatology and Research
Diakonhjemmet Hospital, Oslo, Norway

1 INTRODUCTION

This application outlines the prospective observational study "Early STratification of acute inflammatory ARThritis" (START) which aims at building a platform for development of stratification tools for personalised management of patients with early stage inflammatory arthritis (IA). The heterogeneity of disease presentation, progression and response to therapies in patients with IA makes it difficult for clinicians to successfully treat patients, predict treatment outcome and provide optimal care. Development and implementation of personalised medicine in the healthcare services are strategic goals both nationally and regionally.[1] The current project proposal outlines a project where the applicant and the project group have the expertise, network and infrastructure necessary to fill current knowledge gaps, and to improve management and care for a large group of patients with a potentially disabling disease course.

Figure 1: Conceptual figure- Stratification of early inflammatory arthritis

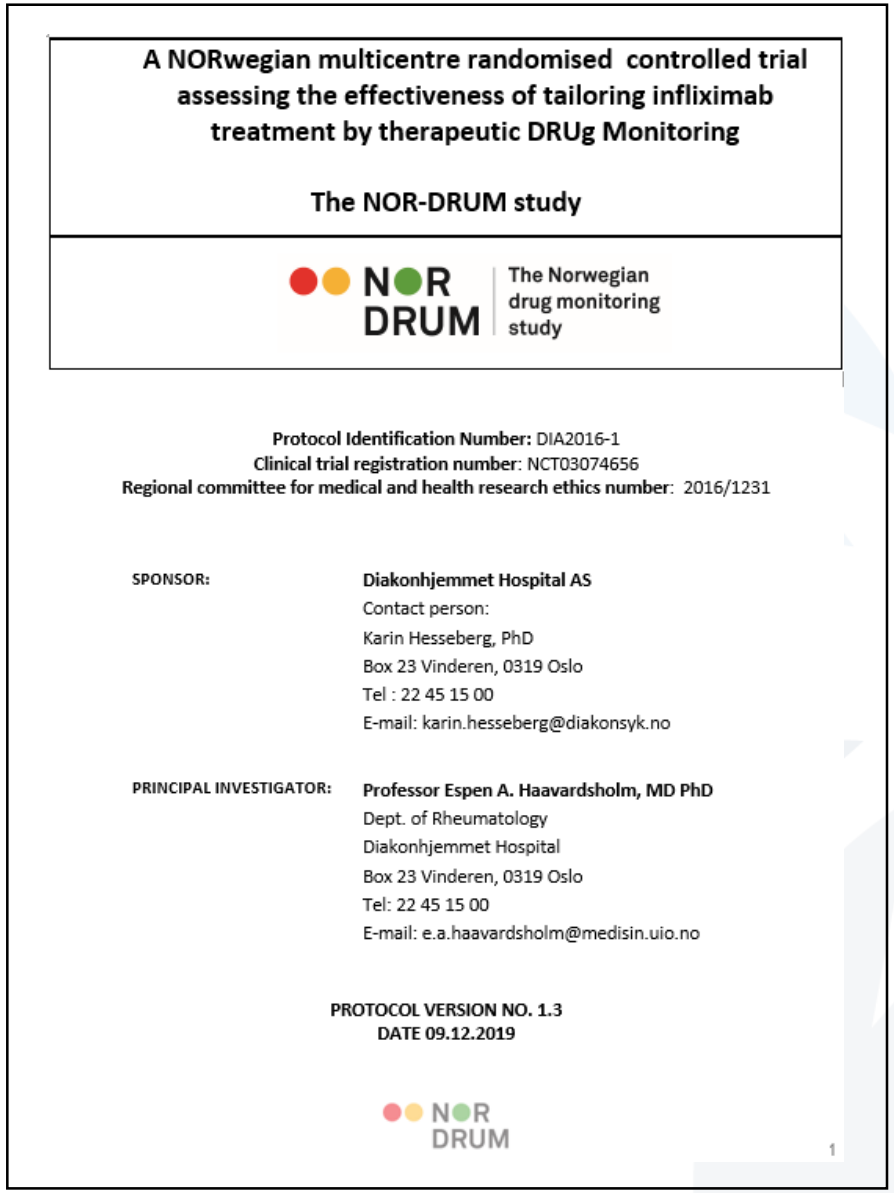
1.1 Background, state of knowledge and description of needs

1.1.1 Inflammatory arthritis

Arthritis is characterised by inflammation of the joint leading to swelling, pain and loss of function. Several conditions may cause IA, such as intraarticular infections, reactive arthritis, crystal disposition and early stage of chronic inflammatory joint diseases such as rheumatoid arthritis (RA), spondyloarthritis (SpA) or psoriatic arthritis (PsA). A significant proportion of both acute and chronic IA remains "undifferentiated" according to current classification criteria.

Protokoll – et lagarbeid

- Dedikert hovedutprøver/prosjektleder
- Styringsgruppe
  - Nasjonale meningsbærere, forskere med erfaring fra kliniske studier, hovedutprøvere, statistikere, klinikere
  - Internasjonalt advisory board
  - Internasjonalt ledende forskere
- Brukerrepresentanter
- Studieleger og studiesykepleiere
- Forankring klinikk



A NORwegian multicentre randomised controlled trial assessing the effectiveness of tailoring infliximab treatment by therapeutic DRUg Monitoring

The NOR-DRUM study

NOR DRUM The Norwegian drug monitoring study

Protocol Identification Number: DIA2016-1
Clinical trial registration number: NCT03074656
Regional committee for medical and health research ethics number: 2016/1231

SPONSOR: **Diakonhjemmet Hospital AS**
Contact person:
Karin Hesseberg, PhD
Box 23 Vinderen, 0319 Oslo
Tel : 22 45 15 00
E-mail: karin.hesseberg@diakonsyk.no

PRINCIPAL INVESTIGATOR: **Professor Espen A. Haavardsholm, MD PhD**
Dept. of Rheumatology
Diakonhjemmet Hospital
Box 23 Vinderen, 0319 Oslo
Tel: 22 45 15 00
E-mail: e.a.haavardsholm@medisin.uio.no

PROTOCOL VERSION NO. 1.3
DATE 09.12.2019

NOR DRUM

1

Diakonhjemmet Hospital

REMEDY

TABLE OF CONTENTS

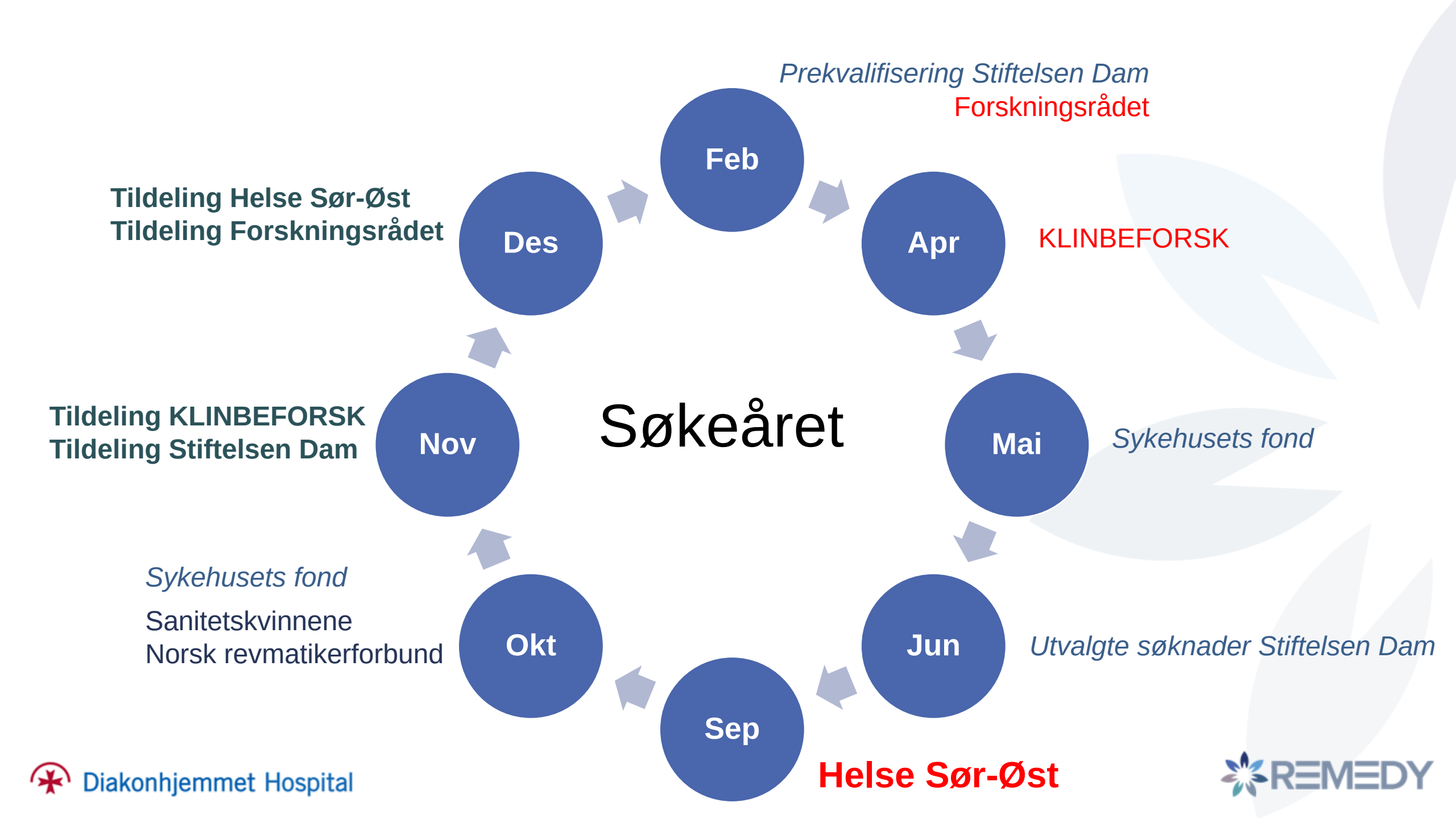
Diakonhjemmet Hospital

REMEDY

Ressurser

- Kliniske studier er kostbart!
- Adekvat finansiering avgjørende
- Nødvendig for å rekruttere studiesentra
  - Studiepersonell
  - Legemiddel
  - Prosedyrer (radiologi, biobanking)
  - Forsikring
  - Monitorering

Økende krav



Diakonhjemmet Hospital

REMEDY

Hvor skal man prøve å søke penger?

Helse Sør-Øst 2020

Tabell 3. Antall søknader innstilt til støtte per søknadskategori.

Søknadskategori	Antall vurderte søknader	Antall innstilte søknader	Beløp (tusen kroner)	
Doktorgradsstipend	268	44	43 322	16%
Postdoktorstipend	115	32	31 596	28%
Karrierestipend	37	7	13 437	19%
Åpen prosjektstøtte	106	16	42 689	15%
Prosjektmidler til klinisk forskning *	11	5	2 875	45%
Totalt	**537**	**104**	**133 919**	

*) *Prosjektmidler til klinisk forskning er beregnet for avgrensede, mindre kliniske forskningsprosjekter, for eksempel oppstarts- eller pilotprosjekter. Kategorien har søknadsadgang begrenset til to søknader per helseforetak eller klinikk ved universitetssykehusene. Det vises her til føringer i utlysningsteksten.*

Forskningsrådet 2018

- FRIMEDBIO fikk 503 søknader om til sammen 4,25 milliarder kroner

	FRIMEDBIO
Forskerprosjekt	31
Unge forskertalenter	12
FRIPRO mobilitetsstipend	5
Totalt	**48 (9,5%)**

Prosjektbeskrivelse: Metodeavsnitt

- **Hvordan besvares forskningsspørsmålet best?**
  - RCT? Mulig bruke allerede innsamlede data?

- **Hva er realistisk å gjennomføre innenfor gitte rammer?**
  - Styrkeberegning
  - NB! Viktigheten av riktig utfallsmål for å optimalisere hvor mange pasienter man må inkludere
  - Multisenter? Fordel og ulemper

- **Hvordan planlegge for god datakvalitet?**
  - Vise forståelse for krav om søknad til REK, CTIS
  - Plan for monitorering dersom legemiddelstudie
  - Ta stilling til CRF-løsning?

Evalueringskriterier

	Project quality	Impact
1	**Originality:** • Scientific novelty /originality relative to the research front of the subject area • Degree of innovation; does the project challenge current practices (clinical and research), e.g. through innovative use of theory/methods?	**Needs justification:** • Target group(s), i.e. patient group(s), carers, other identified users • Needs in the specialist health services • Filling knowledge gaps • Meeting other needs of society
2	**Design of the application:** • Scientific background of the project • Overview of the research front, state-of-the-art, relevant references / literature • Description of hypotheses, objectives and milestones • Description of positions (particularly important for PhD grants) and roles	**Importance of generating new knowledge:** • Realistic importance for the health services, possible improvements of existing offers/practices • Importance of new knowledge / filling knowledge gaps, academic impact • Impact on society, potential for generalisation / broad use of new knowledge
3	**Feasibility:** • Realistic, well-reasoned and appropriate project plans (data collection, methods, analyses, statistics etc.) • Identified risks, alternative strategies for conducting the project • Data available from pilot projects or other preliminary data where relevant • Realistic budgets	**Potential for implementation:** • Realistic plans for implementation / translation of research into improved practice • Realistic time line for implementation (short/long term) • Identified dependencies on development in other areas
4	**Quality of the applicant (relative to career stage):** • Expertise and qualifications • Productivity • Skills related to project management and supervision • Independency relative to career stage (particularly important for career fellowship proposals)	**Competence building:** • Gain of knowledge/skills required in the health services • Development of methods, techniques • Strengthening of the research area
5	**Research environment:** • Infrastructure, access to equipment and resources, necessary/relevant scientific networks • Relevant collaborators • Educational environment, capacity and ability to supervise • Cross-disciplinarity if relevant	**Dissemination and visibility:** • Plan for dissemination; publications, articles, web sites etc. • Plan for user involvement when relevant • Other relevant plans for disseminating new knowledge, nationally and internationally

Helse Sør-Øst

Scientific quality
Project design and originality: ☐ Scientific background of the project, overview of the research front, state-of-the-art, relevant references / literature ☐ Description of hypotheses, objectives and milestones ☐ Description of positions (particularly important if including PhD grants) and roles ☐ Scientific novelty /originality relative to the research front of the subject area ☐ Degree of innovation. Does the project challenge current practices (clinical and research), e.g. through innovative use of theory/methods?
Feasibility: ☐ Realistic, well-reasoned and appropriate project plans (data collection, methods, analyses, statistic strength etc.) ☐ Identified risks, alternative strategies for conducting the project ☐ Data available from pilot projects or other preliminary data where relevant ☐ Realistic budgets
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Mandatory items of the application
Dissemination and visibility: ☐ Plan for dissemination; publications, articles, web sites etc. ☐ Other relevant plans for disseminating new knowledge, nationally and internationally
Plan for user involvement

KLINBEFORSK

Excellence
The extent to which the proposed work is ambitious, novel, and goes beyond the state of the art
- Scientific creativity and originality.
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Potential impact of the proposed research
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- The extent to which the potential impacts are clearly formulated and plausible.

Communication and exploitation
Quality and scope of communication and engagement activities with different target audiences, including relevant stakeholders/users.

Implementation
The quality of the project manager and project group
- The extent to which the project manager has relevant expertise and experience, and has demonstrated the ability to perform high-quality research (as appropriate to the career stage).
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Forskningsrådet

Diakonhjemmet Hospital

REMEDY

Evalueringskriterier

Originalitet/novelty

	Project quality	
1	**Originality:** • Scientific novelty /originality relative to the research front of the subject area • Degree of innovation; does the project challenge current practices (clinical and research), e.g. through innovative use of theory/methods?	**Needs justification:** • Target group(s), i.e. patient group(s), carers, other identified users • Needs in the specialist health services • Filling knowledge gaps • Meeting other needs of society
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- The extent to which the potential impacts are clearly formulated and plausible.

Communication and exploitation
Quality and scope of communication and engagement activities with different target audiences, including relevant stakeholders/users.

Implementation
The quality of the project manager and project group
- The extent to which the project manager has relevant expertise and experience, and has demonstrated the ability to perform high-quality research (as appropriate to the career stage).
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Helse Sør-Øst

Diakonhjemmet Hospital

KLINBEFORSK

Forskningsrådet

REMEDY

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Communication nd exploitation

Quality and scope o communication and engagement activities with different target audiences, including relevant stakeholders, users.

Implementation

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Helse Sør-Øst

Diakonhjemmet Hospital

KLINBEFORSK

Forskningsrådet

REMEDY

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Quality of research questions, methodology

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Quality and scope of communication and engagement activities with different target audiences, including relevant stakeholders/users.

Implementation

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Helse Sør-Øst

Diakonhjemmet Hospital

KLINBEFORSK

Forskningsrådet

REMEDY

Nytte

- Pasient
- Samfunn

Sørg for å beskrive begge deler i søknaden!

Formelle godkjenninger

- Clinical Trials Information System (CTIS)
- Regional Etisk Komite, REK
- Personvernombud
- Lokale forskningsutvalg
- Registrering
  - Eks: clinicaltrials.gov

Lokale forskningsutvalg

Diakonhjemmet Sykehus Administrerende Direktør - Forskningsutvalget - Forskning, kvalitet og registre			Dok.id.: EK.13.6.1.3
Forskningsprosjekter - planlegging og gjennomføring			Versjon:5.00
Dokumenttype: Rutine	Fagansvarlig: Forskningsutvalg	Godkjent av: Administrerende direktør Anders Mohn Frafjord	Gyldig fra: 27.02.2019

Utskrift kun gyldig på utskriftstidspunktet: 26.11.2019

Endringer siden forrige versjon

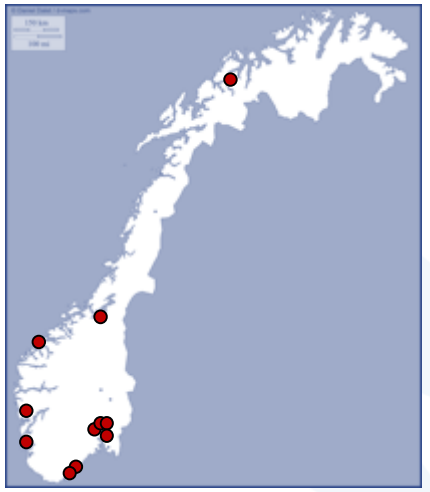
Flere endringer - bl.a. i tråd med registreringssystem for kvalitet og forskningsprosjekter, innføring av personvernombud på sykehuset og trinnvis fremstilling av fremgangsmåte.

1. HENSIKT

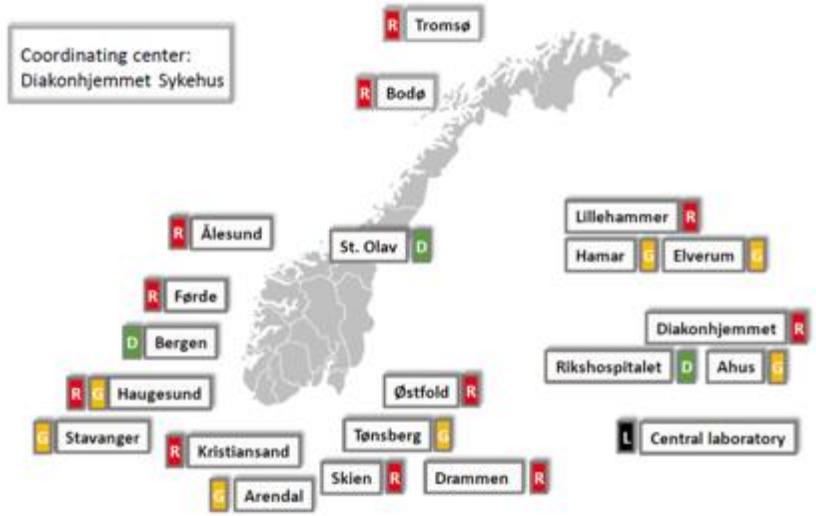
Sikre at planlegging, godkjenning og gjennomføring av medisinsk og helsefaglig forskning ved sykehuset skjer i samsvar med krav i lov og forskrifter.

- På koordinerende senter
- På andre studiesentra

Rekruttering av studiesentre



- **Viktige personer**
  - Avdelingsleder – må være positiv!
  - **Lokal hovedutprøver**
  - Studiesykepleier(e) og studieleger
- **Ressurser og forskningsinfrastruktur**
  - Bildediagnostikk, lab, biobank, apotek, CTU-enhet, monitorer etc
- **Lokale møter for rekruttering av studiesentra**
  - Informasjon
  - Vurdere senteret (motivasjon, personell, ressurser)
  - Mulighet for vitenskapelig samarbeid



Diakonhjemmet Hospital

REMEDY

Rekruttering av studiesentre

PROS

- Bidra til økt kunnskap
- Meritterende
- Nettverk
- Krydre hverdagen
- Dugnadsånd
- Pasientene
- Penger

CONS

- Kapasitet
- Egen forskning på feltet
- Prosjektets relevans

Vellykket rekruttering av studiesentra

- Vær innstilt på reising. Besøk alle studiesentra
- Sørg for finansiering
- Vitenskapelig samarbeid – medforfatterskap, tilgang til data

Diakonhjemmet Hospital

REMEDY

Studiedrift

- Motivasjon
- Senterkontakt
  - Tilgjengelighet
- Nyhetsbrev
- Utprøvermøter
- Datasjekker/regelmessige kontroller av datainnsamlingen
- Samarbeid med monitor/forskningsstøtte
  - Egne monitor-møter

Rekruttering av deltakere

- Inklusjons- og eksklusjonskriterier
  - Eksisterer disse pasientene ved studiesenteret?

- Skriftlig og muntlig informasjon om studien
  - Muntlig viktigst – avgjørende å informere, motivere og inkludere pasienter, få frem positive sider ved studien, informere om potensiell risiko og skade
  - Finansiering
  - Ingen egenandel for studiespesifikke prosedyrer
  - Kompensasjon for reisekostnader/tid?

Elektronisk datainnsamling

- Avgjørende for vellykket studie
- God erfaring med Viedoc

Diakonhjemmet Hospital

REMEDY

Good Clinical Practice (GCP)

- «Internasjonal, etisk, vitenskapelig kvalitetsstandard for design, utførelse, innsamling, dokumentasjon, lagring og rapportering av data i kliniske studier på mennesker»

- Bruk sertifisert elektronisk datainnsamlingsverktøy som legger til rette for GCP
  - Monitorering
- GCP-kursing for alt studiepersonell
  - Oppstartsmøte, NorCRIN, onlinekurs

Analyser

- Flink biostatistiker

- Statistisk analyseplan (SAP)
  - Utvikle og signere før databasen «låses»
  - **Predefiner** alle analyser
  - SAP og protokoll submitteres med studiens hovedresultater
  - Prespesifiserte sekundæranalyser

- Oppdater underveis
  - SAP, protokoll og studieregistrering – med samme opplysninger

ARCTIC REWIND
REmission in rheumatoid arthritis – assessing WIthdrawal of disease-modifying antirheumatic drugs in a Non-inferiority Design

Statistical Analysis Plan Final Version 1.1, 18.06.2019
Analyses of patients who receive synthetic disease modifying antirheumatic drugs

Protocol Identification Number: DIA2012-1 / ver 4_1
EudraCT Number: 2012-005275-14

ARCTIC REWIND

Diakonhjemmet Hospital

Publisering: Hovedresultater

- NEJM:
  - Ultrasound in the management of Rheumatoid Arthritis
- Lancet:
  - Ultrasound in the management of rheumatoid arthritis: results from the randomized controlled ARCTIC trial
- BMJ:
  - Ultrasound in management of rheumatoid arthritis: ARCTIC randomised controlled strategy trial

Viktig å tenke på: Sekundære analyser

EXTENDED REPORT

ARD

First step in the development of an ultrasound joint inflammation score for rheumatoid arthritis using a data-driven approach

Anna-Birgitte Aga,[1] Hilde Berner Hammer,[1] Inge Christoffer Olsen,[1] Till Uhlig,[1] Tore K Kvien,[1] Désirée van der Heijde,[1,2] Hallvard Fremstad,[3] Tor Magne Madland,[4] Åse Stavland Lexberg,[5] Hilde Haukeland,[6] Erik Rødevand,[7] Christian Høili,[8] Hilde Stray,[9] Anne Noraas Bendvold,[10] Dag Magnar Soldal,[11] Gunnstein Bakland,[12,13] Elisabeth Lie,[1] Espen A Haavardsholm[1]

Ann Rheum Dis 2016;**75**:1444–1451.

Concise report

RMD Open

Development of a feasible and responsive ultrasound inflammation score for rheumatoid arthritis through a data-driven approach

Anna-Birgitte Aga[1], Hilde Berner Hammer[1], Inge Christoffer Olsen[1], Till Uhlig[1], Tore K Kvien[1], Désirée van der Heijde[2-1], Hallvard Fremstad[3], Tor Magne Madland[4], Åse Stavland Lexberg[5], Hilde Haukeland[6], Erik Rødevand[7], Christian Høili[8], Hilde Stray[9], Anne Lindtner Noraas [10], Inger Johanne Widding Hansen[11], Gunnstein Bakland[12-13], Siri Lillegraven[1], Elisabeth Lie[1] and Espen A Haavardsholm[1]

BMJ — Aga A-B, *et al*. *RMD Open* 2016;**2**:e000325. doi:10.1136/rmdopen-2016-000325 — eular

RHEUMATOLOGY

Original article

doi:10.1093/rheumatology/key202

Predictors of sustained remission in patients with early rheumatoid arthritis treated according to an aggressive treat-to-target protocol

Nina Paulshus Sundlisæter[1,2], Inge C. Olsen[3], Anna-Birgitte Aga[1], Hilde B. Hammer[1], Till Uhlig[1], Désirée van der Heijde[1,4], Tore K. Kvien[1], Siri Lillegraven[1,*] and Espen A. Haavardsholm[1,2,*]; the ARCTIC study group†

RMD Open — Rheumatic & Musculoskeletal Diseases

ORIGINAL ARTICLE

Comparing the disease course of patients with seronegative and seropositive rheumatoid arthritis fulfilling the 2010 ACR/EULAR classification criteria in a treat-to-target setting: 2-year data from the ARCTIC trial

Lena Bugge Nordberg,[1,2] Siri Lillegraven,[1] Anna-Birgitte Aga,[1] Joseph Sexton,[1] Inge Christoffer Olsen,[1,3] Elisabeth Lie,[1] Hilde Berner Hammer,[1] Till Uhlig,[1] Désirée van der Heijde,[1,4] Tore K Kvien,[1] Espen A Haavardsholm[1,2]

To cite: Nordberg LB,

CONCISE REPORT

Clinical and ultrasound remission after 6 months of treat-to-target therapy in early rheumatoid arthritis: associations to future good radiographic and physical outcomes

Nina Paulshus Sundlisæter,[1,2] Anna-Birgitte Aga,[1] Inge Christoffer Olsen,[3] Hilde Berner Hammer,[1] Till Uhlig,[1] Désirée van der Heijde,[1,4] Tore K Kvien,[1] Siri Lillegraven,[1] Espen A Haavardsholm,[1,2] the ARCTIC study group

Arthritis & Rheumatology

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The impact of ultrasound on the use and efficacy of intra-articular glucocorticoid injections in early rheumatoid arthritis: Secondary analyses from the randomised ARCTIC trial

Lena B. Nordberg, Siri Lillegraven, Anna-Birgitte Aga, Joe Sexton, Elisabeth Lie, Hilde B. Hammer, Inge C. Olsen, Till Uhlig, Désirée van der Heijde, Tore K. Kvien, Espen A. Haavardsholm

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CONCISE REPORT

Patients with seronegative RA have more inflammatory activity compared with patients with seropositive RA in an inception cohort of DMARD-naïve patients classified according to the 2010 ACR/EULAR criteria

Lena Bugge Nordberg,[1] Siri Lillegraven,[1] Elisabeth Lie,[1] Anna-Birgitte Aga,[1] Inge Christoffer Olsen,[1] Hilde Berner Hammer,[1] Till Uhlig,[1] Maria Karolina Jonsson,[1,2] Désirée van der Heijde,[1,3] Tore K Kvien,[1] Espen Andre Haavardsholm,[1] and the ARCTIC working group

RMD Open — Rheumatic & Musculoskeletal Diseases

ORIGINAL ARTICLE

Comparative analyses of responsiveness between the Rheumatoid Arthritis Impact of Disease score, other patient-reported outcomes and disease activity measures: secondary analyses from the ARCTIC study

Karen Holten,[1,2] Joseph Sexton,[1] Tore K Kvien,[1,2] Anna-Birgitte Aga,[1] Espen A Haavardsholm[1,2]

Conventional versus ultrasound treat to target: no difference in magnetic resonance imaging inflammation or joint damage over 2 years in early rheumatoid arthritis

Ulf Sundin, Anna-Birgitte Aga, Øivind Skare, Lena B Nordberg, Till Uhlig, Hilde B Hammer, Désirée van der Heijde, Tore K Kvien, Siri Lillegraven, Espen A Haavardsholm ... Show more

Rheumatology, kez674, https://doi.org/10.1093/rheumatology/kez674

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Research Article | OMERACT 2018: International Consensus Conference on Outcome Measures in Rheumatology, Terrigal, Australia, May 2018 Special Interest Groups, Part 1

Validity and Responsiveness of Combined Inflammation and Combined Joint Damage Scores Based on the OMERACT Rheumatoid Arthritis MRI Scoring System (RAMRIS)

Ulf Sundin, Mikkel Østergaard, Daniel Glinatsi, Anna-Birgitte Aga, Kim Hørslev-Petersen, Merete L. Hetland, Kristian Stengard-Pedersen, Peter Junker, Bo J. Ejbjerg, Paul Bird, Philip G. Conaghan, Siri Lillegraven and Espen A. Haavardsholm

The Journal of Rheumatology September 2019, 46 (9) 1222-1227; DOI: https://doi.org/10.3899/jrheum.181064

Forfatterskap/vitenskapelig samarbeid

- Hovedpublikasjon vs sekundære publikasjoner
  - Legge til rette for at lokale hovedutprøvere har naturlig rolle som medforfattere
- Studiegruppe med PubMed-kreditering
- Nytten av internasjonale medforfattere
  - Både i tidlig og sen fase av studien
  - Fortolkning resultater
  - Implementering

Er kliniske studier verdt innsatsen?

Kliniske studier skal besvare spørsmål som:

- Virker en behandling?
- Virker behandlingen bedre enn andre behandlinger?
- Har den bivirkninger?
- Er behandlingen kostnadseffektiv?

Resultatene fra en vellykket klinisk studie
bør endre klinisk praksis –
da er det verdt innsatsen å gjennomføre studien!

Oppsummering

- Problemstilling
  - Må være klart definert
- Klinisk relevans/pasientgrunnlag/nytteverdi
  - Endre klinisk praksis
- Forankring i sykehuset
  - Følge lokale prosedyrer
- Ressurser (personale, tid)
  - Planlegg nøye
- Forankring i klinikken
  - Involver klinikere, sykepleiere, sekretærer, lab, rtg etc.
- Forfatterskap/vitenskapelig samarbeid
  - Avklare tidlig vs. sent
  - Krav fra finansieringskilde?
- Prosjektskisse
  - Synopsis – fint utgangspunkt
  - Skille mellom prosjektsøknad og full protokoll

Takk for oppmerksomheten!