Dose REduction Strategy Study of TNF inhibitors in Psoriatic arthritis and axial Spondyloarthritis patients.

Gepubliceerd: 27-11-2018 Laatst bijgewerkt: 19-03-2025

The aim of the study is to compare the proportion of patients (for PsA and axSpA together) having LDA at 12 months between a T2T strategy with versus without tapering attempt against a pre-set non-inferiority margin of 20%.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON29006

Bron
Nationaal Trial Register

Verkorte titel
DRESS-PS

Aandoening

- Psoriatic arthritis, Axial Spondyloarthritis, Dose reduction, TNF inhibitors
- Artritis psoriatica, Axiale Spondylartritis, Dosis reductie, TNF remmers

Ondersteuning

Primaire sponsor: Sint Maartenskliniek
Overige ondersteuning: Investigator initiated trial

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The difference in proportion of patients between T2T strategy with or without tapering attempt who are in LDA state (PASDAS ≤ 3.2 and modified BSA ≤ 3% of the skin (PsA), ASDAS < 2.1 (axSpA) and an absence of active extra-axial symptoms) at 12 months follow-up, compared to the prespecified non-inferiority margin of 0.2 (20%).

Toelichting onderzoek

Achtergrond van het onderzoek

Spondyloarthritis, notably psoriatic arthritis (PsA) and axial SpA (axSpA) can successfully be treated with Tumour Necrosis Factor inhibitors (TNFi) therapy. When patients are in low disease activity (LDA), the question arises whether patients may be able to maintain LDA with a lower dose or without TNFi, as overtreatment with TNFi is associated with risk for infections and higher costs. A few non-randomised studies have previously explored the possibility of disease activity guided dose reduction in PsA and axSpA, but data is scarce and evidence from randomised trials is lacking. Also, no cost-effectiveness analysis has been performed to provide insight into the potential cost savings of effective dose reduction of TNFi. In contrast, the safety and efficacy of disease activity guided dose reduction of TNFi have already been shown in Rheumatoid Arthritis (RA), and similar strategy trials in Crohns' disease and psoriasis are ongoing in the Netherlands. The aim of this study is therefore to investigate whether a treat-to-target (T2T) strategy with tapering attempt of TNFi is non-inferior to a T2T strategy without tapering attempt in PsA and axSpA patients having LDA for at least 6 months. In addition, a cost-effectiveness analysis will be performed to assess the cost effectiveness between both groups.

Doel van het onderzoek

The aim of the study is to compare the proportion of patients (for PsA and axSpA together) having LDA at 12 months between a T2T strategy with versus without tapering attempt against a pre-set non-inferiority margin of 20%.

Onderzoeksopzet

3, 6, 9 and 12 months

Onderzoeksproduct en/of interventie

The following dose reduction strategy will be adviced to rheumatologists: For patients allocated to the T2T strategy group with tapering attempt the TNFi dose will be reduced about one third by extending the interval every 3 months from 14 to 21 to 28 days for adalimumab and certolizumab, from 7 to 10 to 14 days for etanercept, from 4 to 6 to 8 weeks for golimumab, after which the TNFi will be stopped For infliximab, the interval will remain 8 weeks but the dose will be reduced every 3 months from 3 to 2.25 to 1.5 mg/kg bodyweight after which infliximab will be stopped When a persistent loss of response/flare occurs, the

treatment is intensified to the last effective interval/dose. Patients allocated to the T2T strategy group without tapering attempt will continue treatment following a standardized protocol that is aimed to maintain LDA, at the discretion of the rheumatologist and patiënt. Patients will have a 12 month follow-up period, which will be extended by an additional 12 months observational period (total 24 months of follow-up).

Contactpersonen

Publiek

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024-3272575

Wetenschappelijk

Sint Maartenskliniek
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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Eligible patients are ≥ 16 years of age at the time of signing the informed consent form AND
1) have peripheral SpA of the psoriatic arthritis subtype diagnosed clinically by the rheumatologist , supported by the Classification Criteria for Psoriatic Arthritis (CASPAR) and/or
2) have axial SpA of the axial spondyloarthritis subtype, supported by the Assessment of SpondyloArthritis international Society (ASAS) classification criteria for axSpA, AND
- Are using full dose, or at least > 50% of the authorized defined daily dose (DDD), of an originator or biosimilar TNFi (adalimumab, certolizumab, etanercept, golimumab, infliximab);
- Patients have to have stable LDA, Psoriatic Arthritis Disease Activity Score (PASDAS) ≤ 3.2 and a skin measure of body surface area involvement (modified BSA) using a target of 3% as used by rheumatologists in clinical practice for PsA and/or Ankylosing Spondylitis Disease Activity Score (ASDAS) < 2.1 and an absence of active extra-axial symptoms such as Crohn’s disease, uveitis, colitis or psoriasis for axSpA, for at least 6 months, or when formal measurements are not available, judgement of physician and patient.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Previous recorded unsuccessful dose reduction of TNFi in the previous 24 months,
- Comorbidities expected to hamper successful dose reduction (e g Crohns disease, Ulcerative colitis, Psoriasis, Uveitis),
- Not able to have 12 months follow-up (life expectancy, planned relocation),
- Not able to measure outcome (language, other limitations)

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	09-01-2019
Aantal proefpersonen:	95
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	27-11-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 49692
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6771
NTR-old	NTR7640
CCMO	NL66181.091.18
OMON	NL-OMON49692

Resultaten

Samenvatting resultaten
Michielsens, C.A.J., Boers, N., den Broeder, N. et al. Dose reduction and withdrawal strategy for TNF-inhibitors in psoriatic arthritis and axial spondyloarthritis: design of a pragmatic open-label, randomised, non-inferiority trial. Trials 21, 90 (2020). https://doi.org/10.1186/s13063-019-4000-5