Baricitinib bij patiënten met reumatoïde artritis

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Non-inferiority of tsDAMRD first versus TNFi first in terms of ACR50 response at 12 weeks

Ethische beoordeling	Niet van toepassing
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON20976

Bron
Nationaal Trial Register

Verkorte titel
PERFECT

Aandoening

Rheumatoid Arthritis

Ondersteuning

Primaire sponsor: prof. dr. M.A.F.J. van de Laar
Overige ondersteuning: This Investigator Initiated Trial is partially funded by own resources and by a financial contribution of Eli Lilly.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary endpoint is non-inferiority of tsDAMRD first versus TNFi first in terms of ACR50 response at 12 weeks

Toelichting onderzoek

Achtergrond van het onderzoek

Outcomes of patients with rheumatoid arthritis (RA) have improved markedly over the last decades, mainly due to the availability of novel biological therapies and the practice of adjusting treatment to ensure that predefined disease activity targets are met and maintained over time, i.e. treat to target (T2T). Despite these developments, sustained disease control still cannot be achieved in a substantial subpopulation of patients in clinical practice. Recently, a new class of so called targeted synthetic disease modifying drugs (tsDAMRD) has become available as a potential additional second line treatment option for patients with RA. However, not much is currently known about the real-world benefits these medications provide when applied within contemporary T2T based management strategies. The study objective is to demonstrate non-inferiority of a T2T strategy in which conventional synthetic disease modifying drugs (csDMARDs) refractory RA patients are initially treated with tsDMARD baricitinib versus the comparable T2T strategy in which patients are initially treated with a biological tumor necrosis factor inhibitor (TNFi) in a pragmatic randomized trial.

Doel van het onderzoek

Non-inferiority of tsDAMRD first versus TNFi first in terms of ACR50 response at 12 weeks

Onderzoeksopzet

Data collection and follow-up will take place at baseline, and 12-weekly thereafter until final follow up at 48 weeks.

Onderzoeksproduct en/of interventie

Patients will be randomized (1:1) to a treatment strategy starting with tsDMARD or a treatment strategy starting with TNFi. Patients will be followed up over the course of 48 weeks with scheduled clinic visits at 0, 12, 24, 36, and 48 weeks, and will also be encouraged to schedule visits if they experience a disease flare or adverse events in between scheduled visits. At each visit, disease activity guided therapeutic adjustments will be made as necessary, with the aim of achieving clinical remission. In both groups, therapeutic adjustments include the option to taper or switch medication, depending on the clinical status of the patient.

Contactpersonen

Publiek

Transparency in Healthcare
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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Clinical diagnosis of RA

Active disease (for example DAS28> 3.2)

Former treatment according to T2T principles, at the discretion of the attending rheumatologist, i.e. past treatment decisions informed by disease activity measurements

Previous use of at least one csDMARD

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Disease duration >5 years

Previous treatment with any biological DMARD or tsDMARD

Contraindication for either TNFi or baricitinib

Latent or active tuberculosis

Active or recurrent infections

3x upper limit of normal ALAT

GFR < 30 ml/min.

Failure to provide written informed consent

Refusal to use effective contraceptive during the study period

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	31-03-2019
Aantal proefpersonen:	200
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7547
Ander register	CMO Regio Arnhem-Nijmegen : 2018-5032

Resultaten