SArilumab Actively Replacing TOcilizumab, an Open label Study

Gepubliceerd: 21-11-2019 Laatst bijgewerkt: 18-08-2022

Switching to sarilumab in patients with rehumatoid arthritis responding well to tocilizumab does not lead to a relevant increase in disease activity and is feasible with a persistence of sarilumab >70% at 6 months

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON22277

Bron
NTR

Verkorte titel
SAARTOOS

Aandoening

Rheumatoid Arthritis

Ondersteuning

Primaire sponsor: Sint Maartenskliniek
Overige ondersteuning: Sint Maartenskliniek

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- Increase in DAS28-CRP from baseline to month 6 compared to the pre-specified non-inferiority margin of 0.6

- Proportion of patients persisting with SRL treatment at month 6, compared to a pre-specified minimum persistence of 70% at month 6

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:
Sarilumab (SRL) and tocilizumab (TCZ) are two anti-IL6-receptor antibodies registered for the treatment of moderate to severe rheumatoid arthritis (RA) in patients not responding or intolerant to one or more disease modifiying anti-rheumatic drugs (DMARDs). Both drugs are similar in design, safety and efficacy. SRL is administered less frequently than TCZ (biweekly rather than weekly), thus reducing the injection burden on patients. Furthermore, the possibility of switching from TCZ to SRL is beneficial in case of adverse effects, for pharmaco-economic reasons, and in case of drug shortages.

Objective:
To investigate the effects of switching from TCZ to SRL in clinical practice for RA patients with stable well controlled disease under TCZ treatment.

Design:
This is an observational cohort with a follow up duration of 6 months that will be conducted at the department of rheumatology of the Sint Maartenskliniek, a tertiary referral center specialized in rheumatology, orthopedics and rehabilitation. Patients responding well to a stable dose of TCZ will be approached with an offer to (voluntary) switch to SRL in order to reduce injection burden and because of better cost effectiveness as part of standard care. Patients who choose to switch, and who consent to this observational study, will be included in this cohort and followed for 6 months after switching in order to evaluate the effects of switching.

Participants:
60 patients with rheumatoid arthritis responding well to a stable dose of TCZ will be included.

Primary outcome:
Co-primary endpoints are the efficacy of switching to SRL in patients responding well to TCZ (defined by the change in DAS28-CRP from baseline to month 6 compared to the prespecified non-inferiority margin of 0.6), and the persistence of switching to SRL in patients responding well to TCZ (defined by the proportion of patients persisting with SRL treatment at month 6, com-pared to a pre-specified minimum persistence of 70% at month 6).

Doel van het onderzoek

Switching to sarilumab in patients with rehumatoid arthritis responding well to tocilizumab does not lead to a relevant increase in disease activity and is feasible with a persistence of

sarilumab >70% at 6 months

Onderzoeksopzet

Baseline, 3 months, 6 months

Onderzoeksproduct en/of interventie

N/A

Contactpersonen

Publiek

Sint Maartenskliniek
Nathan den Broeder

0243659396

Wetenschappelijk

Sint Maartenskliniek
Nathan den Broeder

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Diagnosis of rheumatoid arthritis according to 2010 ACR/EULAR and/or 1987 RA criteria and/or clini-cal diagnosis of treating rheumatologist (18;19)
- Currently treated with either i.v. or s.c. tocilizumab in a dose of (162mg s.c. weekly/per 10 days/per 2 weeks/per 3 weeks or 8 to 4 mg/kg i.v. every 4 to 6 weeks) for at least 6 months
- Stable low disease activity (DAS28-CRP<2.9 or DAS28-CRP<3.5 and clinical judg-ment of low disease activity by treating rheumatologist)
- >16 years of age
- Ability to read and communicate well in Dutch

- Informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- Previous non-response to sarilumab
- Known relevant contraindications for sarilumab such as elevated liver enzymes, low leukocyte or platelet counts or active infection, as judged by the treating rheumatologist.
- no ability to measure the study outcome (e.g. due to limited life expectancy or planned relocation)

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-12-2019
Aantal proefpersonen:	60
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	21-11-2019
Soort:	Eerste indiening

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	NL8174
Ander register	CMO Arnhem-Nijmegen : CMO number: 2019-5828

Resultaten