SArilumab Actively Replacing TOcilizumab, an Open label Study

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22277

Source
NTR

Brief title
SAARTOOS

Health condition

Rheumatoid Arthritis

Sponsors and support

Primary sponsor: Sint Maartenskliniek
Source(s) of monetary or material Support: Sint Maartenskliniek

Intervention

Outcome measures

Primary outcome

- 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

Secondary outcome

Efficacy:
- DAS28-CRP at 0, 3, 6 months
- CDAI at 0, 3, 6 months
- Proportion of patients with a DAS28-CRP<2.9 (LDA), and DAS28-CRP<2.4 (remission) according to the ACR/EULAR criteria at 0, 3, 6 months
- Incidence of flare according to OMERACT flare criteria (DAS28-CRP increase of >1.2 or a DAS28-CRP increase of >0.6 and current DAS28-CRP≥2.9)
- Mean disability as measured by HAQ-DI at 0, 3 and 6 months.

Treatment strategy:
- Treatment persistence: reasons for SRL discontinuation (e.g. lack of effect, adverse effects)
- Use of comedication: corticosteroids (type, dose, start/stop dates) csDMARDs (type, dose, start/stop dates) and NSAIDs (start/stop dates)
- Expectations of sarilumab efficacy from both patient and rheumatologist
- Patient preference for tocilizumab or sarilumab and the reasons for this preference

Safety:
- Occurence of adverse events
- We will register the occurrence of adverse events during the study period using the Common Toxicity Criteria for Adverse Events (CTCAE). Special attention will be given to the occurrence of infections and hypercholesterolaemia.
- Routine safety monitoring of sarilumab, the following will be measured prior to sarilumab start, at week 4-8, and every 12 weeks thereafter: hemoglobin, leucocytes, thrombo-cytes, creatinine, alanine transaminase, alkaline phosphatase and a lipid profile

Anti-drug antibodies and pharmacokinetics:
- Proportion of patients with anti-drug antibodies (ADA) to tocilizumab at baseline
- Proportion of patients with ADA to sarilumab at month 6
- Sarilumab levels at month 3 and month 6 and the time of sampling in relation to the last SRL injection

Study integrity:
- Reasons for dropout and protocol adherence

Study description

Background summary

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).

Study objective

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

Study design

Baseline, 3 months, 6 months

Intervention

N/A

Contacts

Public
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Eligibility criteria

Inclusion criteria

- 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

Exclusion criteria

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)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2019
Enrollment:	60
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	21-11-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL8174
Other	CMO Arnhem-Nijmegen : CMO number: 2019-5828

Study results