The effect of switching treatment from innovator infliximab to infliximab biosimilar on efficacy, safety and immunogenicity in patients with rheumatoid arthritis, spondyloarthritis or psoriatic arthritis in daily clinical care

No registrations found.

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

Summary

ID

NL-OMON24401

Source
NTR

Brief title
BIO-SWITCH

Health condition

Biosimilar, Infliximab, Inflectra, Remsima

Sponsors and support

Primary sponsor: Participating hospitals are:
Sint Maartenskliniek Nijmegen
Maartenskliniek Woerden
Radboud University Medical Centre Nijmegen
Rijnstate Arnhem
Source(s) of monetary or material Support: Sint Maartenskliniek Nijmegen
Maartenskliniek Woerden

Radboud University Medical Centre Nijmegen
Rijnstate Arnhem

Intervention

Outcome measures

Primary outcome

The difference in mean DAS28-ESR and mean DAS28-CRP (for RA and PsA) and mean BASDAI (for SpA) between baseline and follow-up (after 6 and 12 months of treatment with the biosimilar) will be used as primary efficacy endpoint

Secondary outcome

- To compare efficacy (difference in number of patients with low disease activity; DAS28-ESR ¡Ü 3.2 and DAS28-CRP ¡Ü 2.9 in RA and PsA, BASDAI < 4 in SpA) between baseline and after 6 and 12 months of treatment.

- To evaluate the cumulative incidence of RA and PsA patients with a flare at 6 and 12 months follow-up, defined as DAS28-CRP increase > 1.2 or DAS28-CRP increase > 0.6 and current DAS28-CRP ¡Ý 3.2, compared to baseline DAS28-CRP.

- To evaluate the cumulative incidence of SpA patients with a flare at 6 and 12 months follow-up, defined as BASDAI increase > 2 or BASDAI increase > 1 and current BASDAI ¡Ý 4, compared to baseline BASDAI.
- To evaluate safety (adverse events (AEs) and serious adverse events (SAEs)) during the follow-up period.
- To compare immunogenicity (% trough level anti-infliximab antibody positive patients) between baseline and after 6 and 12 months of follow-up.

- If a considerable number of patients will not switch treatment to infliximab biosimilar, the efficacy, safety and immunogenicity profile of the switch group will also be compared with that of the control group.

Study description

Background summary

Background: Taking into account the overall data from the PLANETRA and PLANETAS study, previous positive experiences with switching to a biosimilar, the viewpoint of relevant (inter)national stakeholders and the large cost difference, switching from Remicade to infliximab biosimilar in RA, SpA and PsA patients might be a sensible option. This should be

done in shared decision making with the patient and should be monitored with caution. It is expected that in 2015 a substantial number of patients will switch from Remicade to infliximab biosimilar in daily clinical care. Since regulatory guidelines recommend close monitoring of patients who switch treatment to a biosimilar, we shall collect data on efficacy, safety and immunogenicity in daily clinical care.
Objective: To explore the effect of switching treatment from innovator infliximab (Remicade®) to infliximab biosimilar (Inflectra®, Remsima®) on efficacy, safety and immunogenicity in patients with RA, SpA or PsA in daily clinical care.

Study design: This is an exploratory observational controlled before after multicentre prospective cohort study.

Methods: Based on the treatment protocol of the hospitals, RA, SpA and PsA patients who are currently treated with Remicade will be informed about the option to switch to infliximab biosimilar. Both patients who will switch treatment to infliximab biosimilar (switch group) as patients who will not switch treatment (control group) will be asked to participate in this study. Data will be collected during the outpatient clinical visits performed in usual care during a 12 months follow-up. At baseline (day of the first infusion), patient characteristics and blood samples will be obtained. After 6 and 12 months (+/- 2 months) follow-up data on efficacy will be collected. Safety will be evaluated on the day of each infusion. After 6 and 12 months follow-up (+/- 2 months) a blood sample will be obtained on a scheduled infusion day.

Study objective

To explore the effect of switching treatment from innovator infliximab (Remicade®) to infliximab biosimilar (Inflectra®, Remsima®) on efficacy, safety and immunogenicity in patients with rheumatoid arthritis (RA), spondyloarthritis (SpA) or psoriatic arthritis (PsA) in daily clinical care

Study design

Data will be recorded at baseline and after 6 and 12 months (+/- 2 months) of treatment.

Intervention

Based on the treatment protocol of the hospitals, RA, SpA and PsA patients who are currently treated with Remicade will be informed about the option to switch to infliximab biosimilar. Both patients who will switch treatment to infliximab biosimilar (switch group) as patients who will not switch treatment (control group) will be asked to participate in this study. Data will be collected during the outpatient clinical visits performed in usual care during a 12 months follow-up. At baseline (day of the first infusion), patient characteristics and blood samples will be obtained. After 6 and 12 months (+/- 2 months) follow-up data on efficacy will be collected. Safety will be evaluated on the day of each infusion. After 6 and 12 months follow-up (+/- 2 months) a blood sample will be obtained on a scheduled infusion day.

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Eligibility criteria

Inclusion criteria

1. A clinical diagnosis of either RA, SpA or PsA.
2. Currently being treated with Remicade (1 or more infusions)
3. > 18 years of age
4. Ability to read and communicate well in Dutch
5. Informed consent

Exclusion criteria

None

Study design

Design

Study type:	Observational non invasive
Intervention model:	Crossover
Allocation:	Non controlled trial
Masking:	Open (masking not used)

Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-07-2015
Enrollment:	200
Type:	Actual

IPD sharing statement

Plan to share IPD: Yes

Ethics review

Positive opinion

Date:	13-07-2015
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	NL5139
NTR-old	NTR5279
Other	Submitted to CCMO: not WMO liable : 2015-1867 NIET WMO

Study results

Summary results
https://pubmed.ncbi.nlm.nih.gov/29045077/