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

Gepubliceerd: 13-07-2015 Laatst bijgewerkt: 18-08-2022

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...

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

Samenvatting

ID

NL-OMON24401

Bron
Nationaal Trial Register

Verkorte titel
BIO-SWITCH

Aandoening

Biosimilar, Infliximab, Inflectra, Remsima

Ondersteuning

Primaire sponsor: Participating hospitals are:
Sint Maartenskliniek Nijmegen
Maartenskliniek Woerden
Radboud University Medical Centre Nijmegen

Rijnstate Arnhem
Overige ondersteuning: Sint Maartenskliniek Nijmegen
Maartenskliniek Woerden
Radboud University Medical Centre Nijmegen
Rijnstate Arnhem

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Sint Maartenskliniek
Alfons den Broeder
Nijmegen 6500GM
The Netherlands
+31243659276

Wetenschappelijk

Sint Maartenskliniek
Alfons den Broeder
Nijmegen 6500GM
The Netherlands
+31243659276

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

None

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Cross-over
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	14-07-2015
Aantal proefpersonen:	200
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Ethische beoordeling

Positief advies

Datum:	13-07-2015
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	NL5139
NTR-old	NTR5279
Ander register	Submitted to CCMO: not WMO liable : 2015-1867 NIET WMO

Resultaten

Samenvatting resultaten
https://pubmed.ncbi.nlm.nih.gov/29045077/