Long term prospective observational cohort study of the safety and efficacy of certolizumab pegol in the daily clinical practice of rheumatoid arthritis with emphasis on the lipid profile.

Gepubliceerd: 30-06-2011 Laatst bijgewerkt: 15-05-2024

1. Certolizumab pegol, a TNF inhibitor, has recently been approved in the Netherlands for the treatment of moderate to severe rheumatoid arthritis. As efficacy in daily clinical practice can differ from the clinical (registration) trials, e.g. due...

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

Samenvatting

ID

NL-OMON20435

Bron
Nationaal Trial Register

Aandoening

certolizumab pegol
rheumatoid arthritis
safety
efficacy

In het Nederlands
certolizumab pegol
reumatoide artritis
veiligheid
effectiviteit

Ondersteuning

Primaire sponsor: Reade
Overige ondersteuning: UCB Pharma B.V.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To determinate the efficacy and safety of certolizumab pegol in rheumatoid arthritis patients in daily clinical practice during 48 months.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

1. Certolizumab pegol, a TNF inhibitor, has recently been approved in the Netherlands for the treatment of moderate to severe rheumatoid arthritis. As efficacy in daily clinical practice can differ from the clinical (registration) trials, e.g. due to different patient groups, it is important to monitor the daily clinical practice;

2. Recently provisional evidence has been published for possible beneficial effects of TNF inhibitors on the prevention of cardiovascular disease, which might be mediated through modulation of the lipid profile.

Objective:

To determinate the efficacy and safety of certolizumab pegol in rheumatoid arthritis patients in daily clinical practice during 48 months. In addition, the effect of treatment with certolizumab pegol on the lipid profile will be monitored during this study.

Study design:

Prospective observational cohort study in patients in whom certolizumab pegol is started.

Efficacy and safety data will be collected throughout the study. Lipid profiles will be compared to baseline.

Intervention:

Induction scheme of 400 mg every 2 weeks during 6 weeks, thereafter 200 mg every 2 weeks. Certolizumab pegol is administered by subcutaneous injections.

Main study parameters:

Efficacy will be determined in comparison to baseline measuring disease activity, radiological progression and functional capacity during follow-up.

Safety will be determined by the occurrence of side effects. Changes in lipid profile markers during the four years of treatment will be analyzed versus baseline.

Nature and extent of the burden:

The additional “burden” consists of an extra blood sample taken at moments that this would already have been done in view of routine patient care.

Doel van het onderzoek

1. Certolizumab pegol, a TNF inhibitor, has recently been approved in the Netherlands for the treatment of moderate to severe rheumatoid arthritis. As efficacy in daily clinical practice can differ from the clinical (registration) trials, e.g. due to different patient groups, it is important to monitor the daily clinical practice;

2. Recently provisional evidence has been published for possible beneficial effects of TNF inhibitors on the prevention of cardiovascular disease, which might be mediated through modulation of the lipid profile.

Onderzoeksopzet

-2, 4, 16, 28, 52, 78, 104, 130, 156, 208 and 242 weeks.

Onderzoeksproduct en/of interventie

At screening (week – 2) contraindications for certolizumab pegol treatment will be checked. At week 4, 16, 28 and every 6 months thereafter the following will be determined:

1. Disease activity: Disease activity will be recorded using the clinical score systems such as the DAS28 score and its individual components, RADAI score and the American College of Rheumatology (ACR) response criteria. Functional status will be assessed using the HAQ. Moreover the SF-36 questionnaire will be used and the patient will be asked about their employment status, defined as percentages (full time = 100%, half time = 50% etc). These disease activity assessments are part of our routine patient care. In this line the occurrence of extra-articular manifestations as well as co morbidity will be assessed;

2. Safety: At each visit, adverse events and serious adverse events will be recorded;

3. Laboratory investigations: Routine at each visit: Erythrocyte sedimentation rate (ESR), C-reactive protein (CRP), complete blood count (Hb, Ht, white cell count, platelets), creatinin, liver function tests (AST, ALT and alkaline phosphatase);

4. Lipid profile: Total cholesterol, HDL-cholesterol, LDL-cholesterol, triglycerides, apolipoprotein A, apolipoprotein B.

At each visit reference blood samples will be taken. The samples will be stored coded and may be used for the investigation of immunogenicity, glucose metabolism, supplementary lipid profile measurements etc.

Radiologic investigations:

Radiographs of the hands and feet will be taken at baseline and annually thereafter. Bone mineral density of the hip and lumbar spine will be measured (DEXA) at baseline and after one year. Hole body composition will be measured (DEXA) at baseline and after one year.

Genetics:

All patients in this cohort study will be asked separately for their permission to take reference samples at baseline for research into genetic factors. It will be emphasized that only those genetic factors which are likely to be directly related to the inflammatory processes such as TNF-á, IL-1 and IL-6 polymorphisms will be investigated. This part of the study is in collaboration with the VU medical center and will partly take place at that center.

Other variables:

Other variables to be recorded at baseline are: Age, sex, race, duration of disease, RF IgM and anti-ccp status, medical en family history, current medication, medication history

regarding DMARD therapy, prednisone and biological use.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients with rheumatoid arthritis in whom certolizumab pegol treatment is started;

2. Written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

None, except for the contraindications against certolizumab pegol treatment.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-03-2011
Aantal proefpersonen:	200
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	30-06-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 36770
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2824
NTR-old	NTR2965
CCMO	NL35209.048.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON36770

Resultaten

Samenvatting resultaten
N/A