Research into injecting golimumab less frequently by using increased doses

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Golimumab 100 mg every 1,5 month has similar trough levels to golimumab 50 mg every month; golimumab 100 mg every 2 months has a similar AUC to golimumab 50 mg every month.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21487

Bron
NTR

Verkorte titel
INDIGO

Aandoening

Rheumatoid arthritis (RA), psoriatic arthritis (PsA), axial spondyloarthritis (axSpA)

Ondersteuning

Primaire sponsor: Sint Maartenskliniek
Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Description of peak levels, trough levels and area-under-the-curve (AUC) of the following golimumab regimens: 50 mg every month, 100 mg every one-and-a-half month and 100 mg

every two months, in patients with a rheumatic disease.

Toelichting onderzoek

Achtergrond van het onderzoek

Golimumab is a TNF receptor antagonist, proven effective in the treatment of rheumatoid arthritis, psoriatic arthritis and axial spondyloarthritis, in a dose of 50 mg every month. Apart from the 50 milligram injections, 100 milligram injections are also on the market, registered for patients weighing > 100 kg for whom treatment with 50 milligram is not considered effective. However, 100 milligram injections were also tested on normal-weight patients in the registration studies, proven effective and safe, even on long-term. With the 100 milligram injections being available, a new dosing schedule can be created, in which 100 milligram is given with a prolonged dose interval, which would lead to a lower frequency of injections for patients with the same efficacy.
But, there is not much known on the pharmacokinetics of golimumab 100 mg with a prolonged dose interval in patients with a rheumatic disease, so that such a dosing schedule can not yet be created. Therefore, the aim of this explorative study is to determine pharmacokinetic parameters (peak level, trough level, AUC) of the following golimumab regimens: 50 mg every month (control), 100 mg every 1,5 months (expected similar trough levels to 50 mg every month with a drug half-life of 14 days) and 100 mg every 2 months (expected similar AUC to 50 mg every month).

Doel van het onderzoek

Golimumab 100 mg every 1,5 month has similar trough levels to golimumab 50 mg every month; golimumab 100 mg every 2 months has a similar AUC to golimumab 50 mg every month.

Onderzoeksopzet

Disease activity measurements: baseline, 4 months, 8 months
Golimumab serum level measurements: trough - peak - in between - trough for every regimen in the last cycle

Onderzoeksproduct en/of interventie

1) Golimumab 50 mg every month (1 cycle)
2) Golimumab 100 mg every 1,5 month (2 cycles)
3) Golimumab 100 mg every 2 months (2 cycles)

Contactpersonen

Publiek

Sint Maartenskliniek
Celeste van der Togt

024 3272793

Wetenschappelijk

Sint Maartenskliniek
Celeste van der Togt

024 3272793

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1) rheumatoid arthritis (according to 2010 ACR RA and/or 1987 RA criteria and/or clinical diagnosis confirmed by a rheumatologist)
or psoriatic arthritis (according to CASPAR criteria and/or clinical diagnosis of peripheral SpA of the psoriatic arthritis subtype confirmed by a rheumatologist)
or axial spondyloarthritis (according to ASAS criteria and/or clinical diagnosis confirmed by a rheumatologist)
2) patients using golimumab in the standard dose of 50 mg every month for at least three months with a good clinical response, defined as DAS28-CRP =< 2.6 or PASDAS =< 3.2 or ASDAS =< 2.1
3) Informed consent, >= 16 years old and mentally competent
4) Ability to measure the outcome of the study in this patient (e.g. patient availability, willing and being able to undergo repeated serum samples)
5) Ability to read and communicate well in Dutch

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1) Pregnancy

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	02-03-2020
Aantal proefpersonen:	35
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:	12-02-2020
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	NL8373
Ander register	CMO Arnhem-Nijmegen : CMO 2019-5971

Resultaten