Research into injecting golimumab less frequently by using increased doses

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21487

Source
NTR

Brief title
INDIGO

Health condition

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

Sponsors and support

Primary sponsor: Sint Maartenskliniek
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

1) Efficacy of the two intervention regimens by changes in disease activity (DAS28-CRP, ASDAS or PASDAS) compared to 50 mg every month;
2) Proportion of patients with undetectable golimumab levels and/or antibodies to golimumab;
3) Incidence of AEs, with special interest to injection site reactions;
4) Preference of participants: 50 mg every month or 100 mg with a prolonged interval

Study description

Background summary

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).

Study objective

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.

Study design

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

Intervention

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)

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

1) Pregnancy

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	02-03-2020
Enrollment:	35
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	12-02-2020
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	NL8373
Other	CMO Arnhem-Nijmegen : CMO 2019-5971

Study results