INDIGO: Comparing pharmacokinetic parameters of golimumab 50 mg and golimumab 100 mg with a prolonged dose interval in patients with a rheumatic disease, a within-subject controlled study*

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The aim of this study is to describe pharmacokinetic parameters 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.

Ethical review	Approved WMO
Status	Pending
Health condition type	Autoimmune disorders
Study type	Interventional

Summary

ID

NL-OMON48335

Source
ToetsingOnline

Brief title
INDIGO

Condition

- Autoimmune disorders
- Joint disorders

Synonym
arthritis, rheumatic diseases, rheumatoid arthritis

Research involving
Human

Sponsors and support

Primary sponsor: Sint Maartenskliniek
Source(s) of monetary or material Support: de Sint Maartenskliniek zelf

Intervention

Keyword: Biologicals, Golimumab, Pharmacokinetics, Rheumatic diseases

Outcome measures

Primary outcome

The main endpoint is to describe serum peak levels, trough levels and AUC of golimumab 50 mg every month, 100 mg every one-and-a-half month and 100 mg every two months.

Secondary outcome

Secondary endpoints include efficacy, adverse events, presence of anti-drug antibodies and patient preference.

Study description

Background summary

Golimumab is a TNF-inhibitor, proven effective for rheumatoid arthritis, psoriatic arthritis and axial spondyloarthritis, in a dose of 50 mg every month. For patients with a body weight over 100 kilograms, one-hundred milligram golimumab injections are also authorized when therapy with 50 mg is considered ineffective. With the 100 mg injections available and considered safe, golimumab therapy using 100mg injections with a prolonged dose interval can be constructed, to offer patients an equally effective treatment with fewer injections. More knowledge on the pharmacokinetic parameters of golimumab in patients is needed to construct a certain dosing regimen. Assuming that a doubled dose (100 mg) will lead to at least one additional half-life before the same trough level is reached, compared to a single dose, 100 mg every one-and-a-half month would be equal in trough levels to 50 mg every month,

given a half-life of approximately thirteen days. On the other hand, for the area-under-the-curve (AUC), the dose interval should be doubled, leading to a dosing schedule of 100 mg every two months.

Study objective

The aim of this study is to describe pharmacokinetic parameters 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.

Study design

Open-label within-subject controlled study design.

Intervention

Patients will switch from golimumab 50 mg every month to golimumab 100 mg every one-and-a-half month and 100 mg every two months consecutively, both for two cycles.

Study burden and risks

The risks associated with this study are limited, since patients participating in this study already use golimumab. In the literature, golimumab 100mg every month did show more lymphomas compared to 50 mg. However, this seems caused by confounding by indication due to active rheumatoid arthritis being associated with higher lymphoma risk, and this is also corroborated by systemic reviews showing that use of TNF-inhibitors does not result in increase in lymphoma risk. Also, since in this study golimumab 100mg is dosed every one-and-a-half month and every two months, we expect lower risks than 100 mg every month. Possible risks include adverse events to the 100mg golimumab injection, which could be injection site reactions or systemic adverse events. The burden of patients participating in this study is mainly time investment, including twelve study visits for a total of twelve blood samples (four serum samples for every regime to construct peak level, trough level and AUC) and three disease activity measurements, and any regular or unplanned visits with the rheumatologist. A possible benefit for patients is the opportunity to use golimumab less frequently, and therefore lowering the burden of injection therapy and possibly the chance of injection site reactions. The study also includes societal benefits as in many healthcare systems, the 50 and 100 mg golimumab formulation are flat priced.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Rheumatoid arthritis, psoriatic arthritis or axial spondyloarthritis by fulfilling one of the following:
o Rheumatoid arthritis: either 2010 ACR RA and/or 1987 RA criteria and/or clinical diagnosis of the treating rheumatologist;
o Psoriatic arthritis: Classification Criteria for Psoriatic Arthritis (CASPAR) and/or diagnosed with peripheral SpA of the psoriatic arthritis subtype by a rheumatologist;
o Axial spondyloarthritis: Assessment of SpondyloArthritis international Society (ASAS) classification criteria and/or clinical diagnosis of the treating rheuma-tologist;
• Patients using golimumab in the standard dose of 50mg every month for at least three months with a good clinical response, defined as DAS28-CRP <= 2.6

for RA, or PASDAS <= 3.2 (PsA) or ASDAS <= 2.1;
• Patient informed consent, >=16 years old and mentally competent;
• Ability to measure the outcome of the study in this patient (e.g. patient availability; willing and being able to undergo repeated serum samples);
• Ability to read and communicate well in Dutch.

Exclusion criteria

Pregnancy

Study design

Design

Study phase:	4
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	06-01-2020
Enrollment:	35
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Simponi
Generic name:	Golimumab
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	12-12-2019
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	15-01-2020
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	18-03-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
EudraCT	EUCTR2019-004101-27-NL
CCMO	NL71931.091.19