Determination of tocilizumab trough levels during dose tapering in patients with rheumatoid arthritis (OPTIRA study)

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Primary objectives: - To determine in which percentage of the included patients tocilizumab is successfully tapered or discontinued after 12 months (successful = lower dose than at baseline with a DAS28-ESR

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON53280

Source
ToetsingOnline

Brief title
OPTIRA study

Condition

- Other condition
- Autoimmune disorders

Synonym
chronic inflammatory joint disease, rheumatic disorder, Rheumatoid arthritis

Health condition

gewrichtsaandoeningen

Research involving
Human

Sponsors and support

Primary sponsor: Franciscus Gasthuis & Vlietland
Source(s) of monetary or material Support: stichting BOF van het Franciscus Gasthuis and Vlietland ziekenhuis

Intervention

Keyword: Dose tapering, Rheumatoïd arthritis, Serum trough levels, Tocilizumab

Outcome measures

Primary outcome

The primary endpoints of this study are:

- the percentage of patients in whom tocilizumab is successfully tapered after

12 months (successful = lower dose than at baseline with a concurrent DAS28-ESR

<=3.2).

- the serum concentration range of tocilizumab above which low disease activity

is maintained during tapering of tocilizumab.

Secondary outcome

The secondary endpoints of this study are:

- the mean or median dose reduction or interval extension of tocilizumab

between baseline and 12 months (in mg and percentages).

- the mean or median change in disease activity scores between baseline and 12

months.

Study description

Background summary

Tocilizumab is a frequently used biological in the treatment of rheumatoid arthritis. Previous studies have shown that tocilizumab can be successfully

reduced or discontinued in >=50% of the patients with low disease activity and this may decrease overtreatment and health care costs. However, in some patients, disease activity may increase during tapering which may have been caused by a tocilizumab serum concentration that was too low to maintain low disease activity. For some biologicals used in rheumatoid arthritis, therapeutic drug monitoring has proven to be effective in optimizing clinical response. However, exact reference values for tocilizumab remain unknown. In this study, we hypothesize that tocilizumab can be successfully tapered in a substantial part of the patients and that the disease activity will increase when the tocilizumab serum concentration drops below a certain critical level.

Study objective

Primary objectives:
- To determine in which percentage of the included patients tocilizumab is successfully tapered or discontinued after 12 months (successful = lower dose than at baseline with a DAS28-ESR <=3.2).
- To identify the serum concentration range above which low disease activity is maintained during tapering of tocilizumab.

Secondary objectives:
- To determine the mean or median dose reduction or interval extension between baseline and 12 months (in mg and percentages).
- To determine the mean or median change in disease activity scores between baseline and 12 months.

Study design

Mono-center, single-arm, prospective pilot study

Intervention

Tocilizumab will be tapered every 3 months according to an existing dose optimization protocol for tocilizumab. Tocilizumab trough levels will be measured before every next dose tapering step.

If disease activity increases during tapering, temporarily treatment with NSAIDs or corticosteroids is allowed. If disease activity remains high, tocilizumab will be restarted or increased to the last effective dose. In case disease activity still remains high, the dose will be further increased step by step until the registered dose is reached.

Study burden and risks

Dose tapering of tocilizumab is already part of daily clinical practice. The risk of side effects is not affected or possibly even lower due to dose

reduction of tocilizumab. Different from standard care is that an extra blood sample will be taken before every next dose tapering step. Depending on the success of dose tapering, up to 4 tocilizumab trough levels will be determined per patient. Possible risks of blood sampling are that patients may experience pain or develop a hematoma. In addition, participants may have more control visits in the outpatient clinic of rheumatology (once every 3 months instead of once every 6 months).

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

- >=18 years of age - Diagnosed with rheumatoid arthritis and treated for it in Franciscus Gasthuis and Vlietland - Treated with intravenous or subcutaneous tocilizumab - Low disease activity for at least the last 6 months while using

tocilizumab with a current DAS28-ESR <=3.2. - Sufficient understanding of the Dutch language.

Exclusion criteria

none

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-09-2024
Enrollment:	46
Type:	Actual

Ethics review

Approved WMO Date:	24-07-2023
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
CCMO	NL84135.100.23