Efficacy of TOcilizumab in comparison to Prednisone In Rheumatoid Arthritis patients with insufficient response to disease modifying anti-rheumatic drugs.

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In rheumatoid arthritis (RA) patients with insufficient response to disease modifying anti-rheumatic drugs (DMARDs) it is unknown whether addition of tocilizumab (TCZ) to conventional synthetic (cs) DMARDs has superior efficacy compared to addition...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON29402

Source
Nationaal Trial Register

Brief title
TOPIRA

Condition

- Joint disorders

Health condition

Rheumatoid Arthritis

Research involving
Human

Sponsors and support

Primary sponsor: UMC Utrecht
Source(s) of monetary or material Support: Hoffmann - La Roche

Intervention

Explanation

Outcome measures

Primary outcome

Clinical Disease Activity Index (CDAI)

Secondary outcome

Drug retention, radiographic progression, remission rates, (serious) adverse events, several patients reported outcome measeures (HAQ, EQ5D, PSQI, HADS, FACIT-Fatigue)

Study description

Background summary

In this pragmatic, open-label, multicenter trial, 120 patients suffering from rheumatoid arthritis will be randomized to receive treatment with either tocilizumab (162mg/week subcutaneously), or prednisone (10mg/day orally) in addition to their treatment with conventional synthetic disease modifying antirheumatic drugs (csDMARDs). Follow-up is one year. The primary outcome will be disease activity measured by the clinical disease activity index (CDAI).

Study objective

In rheumatoid arthritis (RA) patients with insufficient response to disease modifying anti-rheumatic drugs (DMARDs) it is unknown whether addition of tocilizumab (TCZ) to conventional synthetic (cs) DMARDs has superior efficacy compared to addition of prednisone. If so, TCZ should be considered instead of prednisone. On the other hand, administration of prednisone may be a highly cost-effective treatment approach.

Study design

Baseline, 1, 2, 3, 6, 9, 12 months.

Intervention

Addition of either tocilizumab (162mg/week subcutaneously) OR prednisone (10mg/day orally)

Contacts

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Eligibility criteria

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

Inclusion criteria

• Able and willing to give written informed consent. • Have sufficient knowledge of the Dutch language to be able to comply with the requirements of the study protocol. • At least 18 years of age. • Diagnosed as having RA and meeting the 2010 ACR/EULAR criteria for RA (Appendix A). • Active RA defined by CDAI>10 and at least 1 swollen joint of the 28 joint count. • On stable treatment with csDMARDs for ≥ 8 weeks prior to the screening visit. • Previous treatment with ≥2 csDMARDs OR previous treatment with ≥1 csDMARD in combination with a maximum of 1 TNF inhibitor (Wash out period: ≥2 weeks before first administration of study medication).

Exclusion criteria

• Having a contraindication for treatment with systemic GCs (as determined by the treating

rheumatologist, in line with regular care). • Having a contraindication for treatment with TCZ, as determined by the treating rheumatologist or as described in the Summary of Product Characteristics (SPC) Paragraph 4.3, page 33. 'Special warnings and precautions for use' as described in the SPC Paragraph 4.4, page 33, should be strictly followed. • Use of systemic GCs (including i.a. GCs) within 4 weeks before the screening visit. • Current use of a bDMARD or tsDMARD. • Previous use of ≥ 2 TNF-inhibitors. • Previous use of any other bDMARD (beside 1 TNFi) or tsDMARD. • Treatment with any investigational agent within 4 weeks prior to the screening visit. • Having any other inflammatory rheumatic disease than RA, except for secondary Sjögren's syndrome. • Female who is pregnant (by anamnesis) or breast feeding, or considering becoming pregnant during the study period.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-10-2019
Enrollment:	120
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Approved WMO

Date:	07-10-2019
Application type:	First submission
Review commission:	METC NedMec

Study registrations

Followed up by the following (possibly more current) registration

ID: 56342
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL8070
CCMO	NL68492.041.19
OMON	NL-OMON56342

Study results