De effectiviteit van tocilizumab in vergelijking met prednison bij patienten met reumatoide artritis

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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...

Ethische beoordeling	Goedgekeurd WMO
Status	Werving gestopt
Type aandoening	Gewrichtsaandoeningen
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON29402

Bron
Nationaal Trial Register

Verkorte titel
TOPIRA

Aandoening

- Gewrichtsaandoeningen

Aandoening

Rheumatoid Arthritis

Betreft onderzoek met
Mensen

Ondersteuning

Primaire sponsor: UMC Utrecht
Overige ondersteuning: Hoffmann - La Roche

Onderzoeksproduct en/of interventie

Toelichting

Uitkomstmaten

Primaire uitkomstmaten

Clinical Disease Activity Index (CDAI)

Toelichting onderzoek

Achtergrond van het onderzoek

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).

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Matthijs van der Leeuw

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Wetenschappelijk

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Paco Welsing

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Deelname eisen

Leeftijd
Volwassenen (18-64 jaar)
Volwassenen (18-64 jaar)
65 jaar en ouder
65 jaar en ouder

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• 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).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• 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.

Onderzoeksopzet

Opzet

Fase onderzoek:	3
Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel
Doel:	Behandeling / therapie

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	02-10-2019
Aantal proefpersonen:	120
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Goedgekeurd WMO

Datum:	07-10-2019
Soort:	Eerste indiening
Toetsingscommissie:	METC NedMec

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 56342
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten