The effect of Sarilumab on periodontitis and related biomarkers in rheumatoid arthritis study

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Sarilumab reduces PD severity in RA patients with PD

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON25212

Bron
NTR

Verkorte titel
SAPERA

Aandoening

rheumatoid arthritis, periodontitis (PD)

Ondersteuning

Primaire sponsor: sanofi-genzyme
Overige ondersteuning: Sanofi Genzyme

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

overall safety
periodontal safety

improvement of periodontal condition

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Anti-IL6 receptor blocking therapy has been associated with reduced inflammation in patients with rheumatoid arthritis (RA), but this has not been shown for RA patients with moderate to severe periodontitis (PD).

Primary objective: to assess the effect of Sarilumab on the periodontal condition in patients with RA and concomitant moderate to severe PD.

Secondary exploratory objectives: PD biomarkers and PD related autoimmune biomarkers.

Doel van het onderzoek

Sarilumab reduces PD severity in RA patients with PD

Onderzoeksopzet

baseline, 1, 3 and 6 months (primary endpoint).

Onderzoeksproduct en/of interventie

sarilumab

Contactpersonen

Publiek

Radboudumc
Rogier Thurlings

0243611111

Wetenschappelijk

Radboudumc
Rogier Thurlings

0243611111

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

RA fulfilling the European League Against Rheumatism (EULAR) 2010 classification criteria.
Active RA is defined as a DAS28-CRP > 2.9 and the presence of active arthritis (≥ 2 swollen joints)
Moderate to severe PD.
Initiation of treatment with Sarilumab.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

smoking
diabetes mellitus type I or II
ositive pregnancy test or breast feeding
antibiotic treatment in the previous 3 months
surgical periodontal therapy within the previous 3 months
fewer than 15 teeth
need for treatment of extensive tooth decay, tooth abscesses or other oral infections, such as teeth needing root canal therapy
serious infections.
opportunistic infection in the preceding 3 months.
Evidence of active or latent bacterial infections at the time enrolment, including subjects with evidence of Human Immunodeficiency Virus (HIV) infection.
Current clinical or laboratory evidence of active tuberculosis (TB).
History of active TB treated within the last 3 years.

Heavy alcohol consumption (>3 drinks/day).
Absolute neutrophil count less than 1 x 109/L.
Platelet count below 50 x 103/µL.
Liver cirrhosis or severe renal insufficiency.
Patients for whom Sarilumab is contra-indicated as described in the local label (SmPc).
Patients currently participating in any interventional clinical trials.
Previous experience with Sarilumab through a clinical trial or regular treatment.
Concomitant use of any biologic DMARDs etanercept, adalimumab, infliximab, anakinra, rituximab, abatacept, tocilizumab, certolizumab, golimumab) or the tsDMARDs tofacitinib, baracitinib or filgotinib or any classical DMARD other than methotrexate or leflunomide.
Concurrent treatment with prednisone > 10 mg orally.

Change in prednisone dosage within 4 weeks before the baseline visit.
Treatment with intra-muscular, intra-articular or intravenous prednisone 4 weeks before the baseline visit.
Uncooperative or any condition that could make the patient potentially noncompliant to the study procedures, etc, and, as applicable in the Netherlands, individuals who are institutionalized due to regulatory or legal order.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-06-2020
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8579
Ander register	CMO Arnhem-Nijmegen : 2019-6031

Resultaten