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

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON25212

Source
NTR

Brief title
SAPERA

Health condition

rheumatoid arthritis, periodontitis (PD)

Sponsors and support

Primary sponsor: sanofi-genzyme
Source(s) of monetary or material Support: Sanofi Genzyme

Intervention

Outcome measures

Primary outcome

overall safety
periodontal safety

improvement of periodontal condition

Secondary outcome

biomarkers of periodontitis and periodontitis associated autoimmunity

Study description

Background summary

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.

Study objective

Sarilumab reduces PD severity in RA patients with PD

Study design

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

Intervention

sarilumab

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2020
Enrollment:	20
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL8579
Other	CMO Arnhem-Nijmegen : 2019-6031

Study results