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Prevalence and severity of periodontitis in patients with rheumatoid arthritis (RA) and the effects of treatment

Submission date 14/07/2017	**Recruitment status** Recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 22/08/2017	**Overall study status** Ongoing	
Last Edited 07/03/2025	**Condition category** Oral Health	

Plain English summary of protocol

Background and study aims
Periodontitis is a chronic inflammatory disease affecting the tissue surrounding the teeth, and if left untreated it may result in bone damage and subsequent tooth loss. The disease is very common worldwide, in Sweden affecting approximately 1/3 of the population. Rheumatoid arthritis (RA) is a lifelong autoimmune disease, where the normally protective immune system attacks the joints, resulting in swelling, stiffness and pain. This incurable disease affects approximately 1% of the world's population, mostly women. Previous studies have shown that patients with RA may have an increased risk of periodontitis in general and that non-surgical periodontal treatment may have beneficial effects on RA disease activity. This study aims to investigate the severity of periodontitis in patients with RA and whether frequent periodontal treatment (every three months) results in the improvement of RA disease activity and periodontal parameters in patients with RA and periodontitis.

Who can participate?
Patients with RA and periodontal disease, ≥ 18

What does the study involve?
Participants receive a dental examination at the beginning of the study. Those with periodontitis will be randomly divided into one of two groups. Those in the first group receive a more frequent periodontal treatment every three months, and those in the second group receive periodontal treatment only at the first visit. The periodontal treatment includes oral hygiene instructions and the removal of plaque and tartar by a dental professional. Patients with severe periodontitis in need of specialist treatment are referred to and treated by a dentist who specializes in periodontal disease/a periodontist.

What are the possible benefits and risks of participating?
The main benefits of participating in the study include surveillance and treatment of the periodontal disease performed frequently (every three months) by a dentist. Also, the patients in the control group benefit from conventional periodontal treatment at the inclusion in the study. The side effects of periodontal treatment include sore gums and gum recession due to

reduced inflammation. This is a low-risk study since all the participants receive conventional periodontal treatment during the first visit as well as surveillance of the periodontitis throughout the course of the study.

Where is the study run from?
Karolinska University Hospital (Sweden)

When is the study starting and how long is it expected to run for?
May 2009 to December 2027

Who is funding the study?
Partly funded by the Stockholm County Council, the collaborative European Union's FP7 Research Project TRIGGER, Karolinska Institutet, the Swedish Research Council, the Swedish Dental Society and others.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2009/792-31/4

Study information

Scientific Title
The severity of periodontitis and the effects of periodontal treatment on disease activity of patients with rheumatoid arthritis as well as the influence of medication on periodontitis: A randomized controlled trial

Acronym
Periodontitis in RA (PEIRA)

Study objectives
The hypotheses of this study are:
1. Severe form of periodontitis is more common in seropositive (ACPA/RF) patients with RA as compared to seronegative.
2. Frequent periodontal treatment reduces rheumatoid arthritis disease activity, and related autoimmune and inflammatory parameters.
3. The microbial profile differs based on rheumatological and/or periodontal characteristics in patients with RA.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Regional Ethical Review Board Stockholmm, 10/06/2009, ref: Dnr 2009/792-31/4
2. Regional Ethical Review Board Stockholmm, 30/04/2015, ref: 2015/766-32

Study design
Prospective randomized interventional clinical controlled trial

Primary study design
Interventional

Secondary study design

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Periodontitis and Rheumatoid Arthritis

Interventions
After a full-mouth dental and periodontal examination, participants with periodontitis are randomized to one of two groups.

Those in the first group receive conventional periodontal treatment only at the time of inclusion into the study (control group).

Those in the second group undergo the periodontal treatment every three months (intervention group) for one year year. The conventional periodontal treatment includes oral hygiene instructions, supra- and subgingival scaling and root planning. Patients in need of specialist treatment (e.g. surgical periodontal treatment) are remitted to periodontal clinic.

Participants are assessed for their rheumatoid arthritis activity at baseline and at the study end. Participants are also evaluated for their periodontal parameters such as probing pocket depth, clinical attachment loss, antibodies, microbial profiles and inflammatory mediators.

Intervention Type
Other

Primary outcome measure
1. Rheumatoid arthritis (RA) disease activity is measured using the DAS28 score, HAQ score at baseline and one year
2. Periodontal parameters (such as probing pocket depth, clinical attachment loss) are measured using the methods of measurement of periodontal disease/parameters at baseline and months three, six, nine, and twelve

Secondary outcome measures
1. The microbial profile is assessed using sequencing technology throughout the study (the specific time points depend on the availability of the resources as well as the instruments at core facility)
2. Antibody levels (such as ACPA/RF, periodontal pathogens etc) are measured using multiplex immunoassay, nephelometry and/or ELISA technique at baseline and one year
3. Levels of inflammatory mediators are measured using Luminex immunoassay at baseline and one year

Overall study start date
01/05/2009

Completion date
31/12/2026

Eligibility

Key inclusion criteria
1. ≥ 18 years of age
2. Fulfilling the 2010 ACR criteria for RA
3. Moderate to severe periodontitis, defined according to the classification criteria of the CDC Working Group meant for usage in Population-Based Surveillance of Periodontitis
4. Written informed consent to participate
5. Swedish national registration number

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
150

Key exclusion criteria
1. Antibiotic treatment ≤3 months prior to inclusion into the study
2. Periodontal treatment (surgical or non-surgical) ≤3 months prior to inclusion into the study
3. Pregnancy
4. Simultaneous participation in other interventional studies

Date of first enrolment
01/12/2015

Date of final enrolment
31/12/2026

Locations

Countries of recruitment
Sweden

Study participating centre
Rheumatology Clinics at Karolinska University Hospital (Huddinge and Solna)
141 86 Stockholm (Huddinge)
171 76 Stockholm (Solna)
Stockholm
Sweden
141 86

Sponsor information

Organisation
Karolinska Institutet

Sponsor details
Karolinska Institutet
Deptartment of Dental Medicine
Huddinge
Stockholm
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Sponsor type
University/education

ROR
https://ror.org/04hmgwg30

Funder(s)

Funder type
Not defined

Funder Name
Stockholms Läns Landsting

Funder Name
Vetenskapsrådet

Alternative Name(s)
Swedish Research Council, VR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Sweden

Funder Name
Swedish Dental Society

Funder Name

Swedish Rheumatic Foundation

Funder Name
Karolinska Institutet

Alternative Name(s)
Karolinska Institute, KI

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Sweden

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal with intent to publish 2019/2020

Intention to publish date
31/12/2027

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date