De wisselwerking tussen reumatoïde artritis en de weefsels in en rond de mond.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23256

Source
NTR

Brief title
ReAct

Health condition

Rheumatoid arthritis, temporomandibular joint dysfunction, periodontitis.

Sponsors and support

Primary sponsor: Academisch Centrum Tandheelkunde Amsterdam (ACTA)
Source(s) of monetary or material Support: Academisch Centrum Tandheelkunde Amsterdam (ACTA)

Intervention

Outcome measures

Primary outcome

- Temporomandibular Joint Dysfunction diagnosed according to the DC/TMD criteria, additional static muscle tests and dynamic joint tests on the temporomandibular joint.

- Presence or absence of serological precursors of rheumatoid arthritis: IgM-RF and ACPA serum levels.

Secondary outcome

- Microbiological composition: saliva, tongue coating and dental plaque composition.

- Quantity of fluorescent dental plaque in relation to nutrition: taking fluorescence photographs of the teeth using a dedicated fluorescence camera and filling in a food questionnaire during two days prior to the first research visit.

- Periodontal health: level of bleeding on probing, gingival recessions (positive and negative), dental pocket depth (in mm) and presence / absence of dental plaque, all measured on six sites for each tooth.

- Immuno-biochemical characteristics: gingival crevicular fluid.

- Oral health: amount of decayed, missing and filled teeth, and mucosal lesions.

- General health: standardized health questionnaire, with additional questions about recent use of antibiotics and pain killers.

- Oral Health Impact Profile: short validated OHIP 4 questionnaire.

- Patient reported outcomes of physical function, pain and global status: RAPID questionnaire.

Study description

Background summary

The overall subject of this project is the interaction between rheumatoid arthritis and the orofacial tissues, being explored in a multicenter, observational prospective cohort study. In this study three groups will be compared: (1) patients with an early stage of rheumatoid arthritis, (2) patients with an increased risk of developing this disease, and (3) a control group with no auto-immune conditions. The groups will be compared on several intra- and extra-oral aspects: the temporomandibular joint, the presence and composition of dental plaque, bacteria in saliva and on the tongue, and periodontal condition. At baseline, possible differences in the oral microbiome and prevalence of diseases of the orofacial tissues will be studied. Over time, at 6 months, 1 year, 2 years and 3 years after baseline, this study will focus on the general health of subjects, with specific interest in the possible development of RA in group 2 and the RA disease status of patients in group 3.

All patients will be recruited in the Netherlands, with groups 1 and 2 being recruited at Reade (a center for revalidation and rheumatology in Amsterdam), and group 3 at the Academic

Centre for Dentistry Amsterdam.

Study objective

The aim of this research is to compare patients with early rheumatoid arthritis and patients with an increased risk of developing this disease to a control group with no auto-immune conditions on the prevalence of diseases of the orofacial tissues. Participants will be compared on several intra-oral and extra-oral aspects: the temporomandibular joint, the presence and composition of dental plaque, bacteria in saliva and on the tongue, and periodontal condition. New insights gained from this research might be useful during monitoring and treatment of patients with (an increased risk of developing) rheumatoid arthritis.

Study design

- Temporomandibular Joint Dysfunction: baseline.

- Serological precursors for rheumatoid arthritis: baseline.

- Microbiological composition: baseline. Within group 2 (patients with an increased risk of developing RA), a subgroup will be recognized, consisting of patients taking part in an already ongoing study (NL47550.048.13) on the effects of statins on the development of RA. In these patients, an extra timepoint at 3 months and 6 months after baseline will be added for the microbiological composition.

- Quantity of fluorescent dental plaque in relation to nutrition: baseline.

- Periodontal health: baseline (and a short evaluation of periodontal health at 3 months and 6 months for the subgroup in group 2).

- Immuno-biochemical characteristics: baseline.

- Oral health: baseline.

- General health: baseline, 6 months, 1 year, 2 years, 3 years.

- Oral Health Impact Profile: baseline.

- Patient reported outcomes of physical function, pain and global status: baseline

Intervention

This is an observational study, no intervention takes place.

Contacts

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Eligibility criteria

Inclusion criteria

- Adult, ≥ 18 years

- A minimum of 12 natural teeth present in the mouth

- Willing and able to give written informed consent in the Dutch language

Additional inclusion criteria group 1 (rheumatoid arthritis patients):
- Diagnosis of RA according to the treating rheumatologist: increased serum levels of IgM-RF or ACPA combined with 2 swollen joints or serum levels of both IgMRF and ACPA combined with 1 swollen joint within the last year.
Additional inclusion criteria group 2 (individuals at increased risk of RA):
- Increased serum levels of IgM-RF or ACPA

Exclusion criteria

- ACTA dental students

- Employees from ACTA or Reade

Additional Exclusion criteria group 3 (control group):

- General health: no autoimmune conditions

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-11-2017
Enrollment:	175
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	11-05-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 47476
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6198
NTR-old	NTR6362
CCMO	NL61521.048.17
OMON	NL-OMON47476

Study results