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

Gepubliceerd: 11-05-2017 Laatst bijgewerkt: 15-05-2024

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....

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON23256

Bron
NTR

Verkorte titel
ReAct

Aandoening

Rheumatoid arthritis, temporomandibular joint dysfunction, periodontitis.

Ondersteuning

Primaire sponsor: Academisch Centrum Tandheelkunde Amsterdam (ACTA)
Overige ondersteuning: Academisch Centrum Tandheelkunde Amsterdam (ACTA)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- 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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

- 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

Onderzoeksproduct en/of interventie

This is an observational study, no intervention takes place.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- ACTA dental students

- Employees from ACTA or Reade

Additional Exclusion criteria group 3 (control group):

- General health: no autoimmune conditions

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	22-11-2017
Aantal proefpersonen:	175
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	11-05-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 47476
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten