

Periodontitis and Rheumatoid Arthritis; a link by protein citrullination? A cross-over clinical trial

Published: 24-06-2011

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To assess periodontitis-with P. gingivalis in particular- as a pathogenic factor in disease progression of RA.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Allergic conditions
Study type	Interventional

Summary

ID

NL-OMON36017

Source

ToetsingOnline

Brief title

Periodontitis-RA, cross-over clinical trial

Condition

- Allergic conditions
- Bacterial infectious disorders

Synonym

gum disease, periodontal disease

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Periodontitis, Rheumatoid arthritis

Outcome measures

Primary outcome

Disease Activity Score 28 joint count (DAS28)

Secondary outcome

Periodontal Inflamed Surface Area (PISA)

ACPA titer

Leucocyte count, CRP and ESR.

Presence of *P. gingivalis* in microbial plaque

Study description

Background summary

Periodontitis, with *Porphyromonas gingivalis* in particular, is considered to be of influence on disease progression of rheumatoid arthritis (RA), by inflammatory burden posed by this microbial challenge and protein citrullination by *P. gingivalis*. If there is a distinct relation between these two diseases, treatment of periodontitis would be of influence on RA disease progression.

Study objective

To assess periodontitis-with *P. gingivalis* in particular- as a pathogenic factor in disease progression of RA.

Study design

A cross-over clinical trial on periodontal therapy of RA patients with generalized severe periodontitis, analysing clinical parameters and biomarkers of both diseases. The intervention will be non-surgical periodontal treatment and antimicrobial therapy.

Intervention

Non-surgical periodontal treatment and systemic antimicrobials.

Study burden and risks

There are no risks associated with participation. The potential benefit to participants will be treatment of periodontitis.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

RA patients

1. Fulfilling the American College of Rheumatology classification criteria for RA (1987)
2. Age > 18 years
3. Fulfilling the classification criteria of periodontal diseases for generalized severe chronic periodontitis according to the 1999 International Workshop for Classification of Periodontal Diseases and Conditions

Exclusion criteria

1. Infection or inflammation other than periodontitis or RA
- 2 Present malignancy
3. Other conditions which influence the immune system: diabetes, active thyroid disease, myocardial infarction, stroke or recanalisation of the femoral arteries for claudication <6 months prior to the study
4. Pregnancy including a 6-months post-partem period as well as breastfeeding
5. Malnutrition
6. Alcoholism and drug abuse
7. Pharmacological interference: use of corticosteroids >10mg/dag, antibiotic use during 3 months prior to the study, allergy to amoxicillin or metronidazole
8. Edentulism

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	15-07-2011
Enrollment:	70
Type:	Actual

Ethics review

Approved WMO

Date: 24-06-2011

Application type: First submission

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

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
CCMO	NL36030.042.11