

Periodontitis and Rheumatoid Arthritis; a link by protein citrullination? Presence of Anti Citrullinated Protein Antibodies (ACPAs) in periodontitis.

Published: 17-02-2011

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To determine the presence of ACPAs in patients with generalized severe periodontitis. Second objective is to assess RA development of ACPA positive periodontitis patients in the future.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Autoimmune disorders
Study type	Observational invasive

Summary

ID

NL-OMON36598

Source

ToetsingOnline

Brief title

ACPAs in periodontitis

Condition

- Autoimmune disorders
- 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: ACPAs, Periodontitis, Rheumatoid arthritis

Outcome measures

Primary outcome

ACPA titer

Secondary outcome

Periodontal inflamed surface area (PISA), presence of P. gingivalis, and development of clinical symptoms of RA.

Study description

Background summary

Because of the presumed relation between rheumatoid arthritis (RA) and periodontitis by protein citrullination, we want to know if anti-(cyclic) citrullinated protein antibodies (ACPAs or anti-CCP antibodies), are present in patients with periodontitis. The presence of ACPAs in combination with undifferentiated arthritis is highly predictive for the development of RA.

Study objective

To determine the presence of ACPAs in patients with generalized severe periodontitis. Second objective is to assess RA development of ACPA positive periodontitis patients in the future.

Study design

Prospective observational cohort study. Peripheral blood will be drawn from patients with generalized severe periodontitis, otherwise in systemically healthy condition. If the patients is ACPA positive, follow-up at the rheumatology department is advised, for determining future development of clinical RA symptoms.

Study burden and risks

Since ACPA positive patients in combination with undifferentiated arthritis can be at risk for development of RA, they will be referred to the rheumatology department.

Contacts

Public

Universitair Medisch Centrum Groningen

Antonius Deusinglaan 1
9713AV
NL

Scientific

Universitair Medisch Centrum Groningen

Antonius Deusinglaan 1
9713AV
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

1. Fulfilling the classification criteria of periodontal diseases for generalized severe periodontitis according to the 1999 International Workshop for Classification of Periodontal Diseases and Conditions
2. Age > 18 years

Exclusion criteria

According to the SENIEUR protocol (1984)

1. Infection or inflammation other than periodontitis.
2. Malignancy, past or present
3. Other conditions which influence the immune system: RA, 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. Use of corticosteroids >10mg/day, antibiotic use during 3 months prior to the study
8. Edentulism

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2010
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO	
Date:	17-02-2011

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO	
Date:	18-07-2012
Application type:	Amendment
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	NL31383.042.10