Periodontitis and Rheumatoid Arthritis; a link by protein citrullination? An observational study.

Published: 24-06-2011
Last updated: 28-04-2024

Confirm an association between RA and periodontitis and unravel pathogenic mechanisms underlying this association.

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

Summary

ID

NL-OMON36011

Source
ToetsingOnline

Brief title
Periodontitis-RA, observational study.

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: Periodontitis, Rheumatoid arthritis

Outcome measures

Primary outcome

The Dutch Periodontal Screenig Index (DPSI) (van der Velden 2009).

Secondary outcome

Disease Activity Score 28 joint count (DAS28)

Eastman Interdental Bleeding Index (EIB, Caton&Polson 1985)

Visible plaque index (VPI, Ainamo&Bay 1975)

ACPA titer

Anti-Pg titer

Presence of Porphyromonas gingivalis

Presence of ACPAs in gingivocrevicular (GCF)

Presence of HLA DR/DQ

Leucocyte count, ESR, CRP

Study description

Background summary

Rheumatoid arthritis (RA) and periodontitis are chronic inflammatory disorders characterized by disregulation of the host inflammatory response. Increased secretion of proinflammatory mediators results in soft and hard tissue destruction of the synovium and periodontium respectively. The etiology of both diseases is multifactorial, and they share risk factors like smoking, ageing and certain ge-polymorphisms. Studies have shown the prevalence of periodontitis is higher in RA patients, and that periodontal therapy can reduce the disease activity of RA. Sequence similarity and cross-reactivity with immunodominant epitopes of citrullinated proteins and their bacterial variants, and/or molecular mimicry of antibodies may indicate a role for bacterial

infection, particularly with the periodontal pathogens P. gingivalis, in priming autoimmunity in a subset of patients with RA.

Study objective

Confirm an association between RA and periodontitis and unravel pathogenic mechanisms underlying this association.

Study design

An observational study on the prevalence of periodontitis in RA patients, analysing clinical parameters and biomarkers of both diseases. Biomarkers will be assessed in peripheral blood, subgingival plaque and gingivocrevicular fluid. In case of periodontal or orthopaedic surgery this will also be done in gingival and synovial tissue.

Study burden and risks

Potential benefit: detection 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

Study group: RA patients
1. Fulfilling the American College of Rheumatology classification criteria for RA (1987).
2. Age > 18 years.
Control group: individuals without RA, aged >18 years.

Exclusion criteria

According to the SENIEUR protocol (1984):
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.
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:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-07-2011
Enrollment:	75
Type:	Actual

Ethics review

Approved WMO

Date:	24-06-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Not approved

Date:	16-01-2013
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	NL36033.042.11