Periodontitis and Rreumatoid arthritis- association, dual treatment and resolution study

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To investigate the pathophysiological link between RA and PD, and test the efficacy of RvE1 treatment in gingival tissue biopsies of RA-PD and RA risk-PD patients ex vivo.

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

Summary

ID

NL-OMON43308

Source
ToetsingOnline

Brief title
PARASOLVE

Condition

- Autoimmune disorders
- Bacterial infectious disorders
- Synovial and bursal disorders

Synonym
destructive inflammation of periodontal ttisues, periodontitis

Research involving
Human

Sponsors and support

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

Intervention

Keyword: paradontitis, resolution, rheumatoid arthritis, treatment

Outcome measures

Primary outcome

the effect of resolvin E1 on T helper 17 activation and pro-inflammatory cytokines in gingival, blood and synovial tissue from RA patients and on gingival tissue and blood of patients at risk for RA.

Secondary outcome

Presence, isotype and fine specificity of ACPA, arginin control antibodies and anti-P.gingivalis antibodies, bacterial cell numbers and products and key inflammatory cytokines and chemokines in gingival tissue and synovial tissue of patients with PD and RA and patients with PD at risk for RA.

Study description

Background summary

Rheumatoid arthritis and periodontitis are prevalent chronic conditions associated with significant morbidity. Both conditions are characterized by chronic inflammation and local tissue destruction. Evidence from our and other groups indicates that RA and PD not only often concur, but may also have a shared etiopathogenesis. The production of inflammatory and microbial particles during PD may enhance arthritogenic immune activation. Furthermore, PD may induce a break in immune tolerance in genetically predisposed individuals, resulting in production of the RA-defining anti-citrullinated peptide antibodies (ACPA) and elevated Th17 subset responses.
It is clinically highly relevant to investigate whether RA disease activity can be diminished by oral treatment of PD. Current treatment options for PD are limited, and for RA are not always adequate and associated with immunosuppressive side effects. Recently, key findings in the mechanisms of inflammation indicate that resolution of inflammation is steered by biochemical mediators, termed pro-resolving mediators, that enable inflamed tissue to return to homeostasis. Oral application of the pro-resolving mediator resolvin

E1 (RvE1) was shown to prevent onset and progression of experimental acute PD. Of importance and in contrast to immunosuppressants RvE1 increased clearance of PD-associated bacteria. Therefore, RvE1 is an interesting candidate drug to be investigated in a new oral treatment modality for the dual treatment of PD and RA.
Despite the experimental effectiveness of RvE1 for PD, it is unclear whether periodontal treatment with RvE1 will diminish RA disease activity. On the one hand, PD may be only involved in the initiation of RA and disease progression might be driven by PD-independent inflammatory mechanisms. On the other hand, systemic inflammatory innate and adaptive immune mechanisms may be shared between inflamed periodontium and synovium independent of the disease phase. We hypothesize that RA and PD are pathophysiologically linked, and that periodontal treatment with RvE1 reduces both PD and arthritis by attenuating the shared adaptive inflammatory response and reducing oral bacterial cell numbers.

Study objective

To investigate the pathophysiological link between RA and PD, and test the efficacy of RvE1 treatment in gingival tissue biopsies of RA-PD and RA risk-PD patients ex vivo.

Study design

Study design: A mechanistic biologic analysis in transversal patient cohorts.

Intervention: questionnaire, blood sampling, gingival tissue biopsy and for RA patients willing to undergo a second procedure: an ultrasound guided synovial biopsy.

Study burden and risks

1. vene punction: In a proportion of persons undergoing vene punction a hematoma can occur.
2. gingiva biopsy: In a proportion of persons undergoing gingival biopsy a hematoma can occur.
3. ultrasound guided synovial biopsy: In a proportion of persons undergoing a synovial biopsy a hematoma can occur.

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

(N<=20 per group)
1. early, untreated rheumatoid arthritis (RA) patients with peridontitis (PD)
2. early, untreated RA patients without PD
3. matched PD patients as controls
4. RA risk individuals with PD
5. RA risk individuals without PD.

Exclusion criteria

active infectious or other inflammatory disease

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-05-2017
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	20-07-2016
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	16-08-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL57194.091.16