The effect of periodontitis on innate immune activation and vascular wall inflammation in relation with atherosclerosis

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON44156

Source
ToetsingOnline

Brief title
PERIO-IIM

Condition

- Other condition
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
Gum disease

Health condition

parodontitis

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Horizon 2020 grant van de Europese Unie

Intervention

Keyword: Atherosclerosis, Inflammation, Periodontitis, Trained innate immunity

Outcome measures

Primary outcome

The main study parameter will be to correlate tissue inflammation, measured by

TBR max with 18F-FDG on PET-CT scanning of periodontal tissue with the vascular

wall, spleen and bone marrow in patients with versus without periodontal

disease.

Secondary outcome

The cytokine/chemokine response to ex vivo stimulation of the innate immune

cells in patients with versus without periodontal disease.

Study description

Background summary

Over 25 years of accumulating evidence shows that there is an association between periodontal disease and cardiovascular disease. In 2012, the American Heart Association stated that periodontitis (PD) is considered as an independent risk factor for cardiovascular disease (CVD). The relationship between PD and CVD is potentially of great public health importance due to the high prevalence and economic burden of both diseases. For example, each year 17.5 million people die of cardiovascular diseases, and the prevalence of moderate to severe periodontitis is as high as 40% worldwide.
However, the exact mechanistic link between periodontal disease and cardiovascular disease remains unresolved. Several possible mechanisms have

been proposed to explain this association, however a comprehensive understanding has not yet been developed. To our knowledge, both periodontitis and atherosclerosis are chronic low grade inflammatory diseases involving a close interaction with the innate immune system. In this research proposal we hypothesize a new mechanism involving the innate immune system which might elucidate the bilateral associations between cardiovascular disease and periodontal disease. This study investigates the role of infection and inflammation in atherosclerosis which might unravel new therapeutic options for patients with periodontitis in the near future and gain new insight in the understanding of atherosclerosis.

Study objective

The main objective of this study is to investigate whether a long lasting pro-inflammatory phenotype, the characteristic of trained immunity, is present in circulating monocytes of patients with severe periodontal disease and whether this correlates with vascular wall inflammation and bone marrow activity.

Study design

A prospective observational study.

Study burden and risks

In our opinion the risk of participation in this study is very low.
Participants will receive vene puncture and PET-CT scanning. Both procedures are part of standardized medical care and considered safe. Vene puncture is known for minor self-limiting side-effects, namely a hematoma. PET imaging with low-dose-CT may reveal unanticipated pathology, and exposes the patients to radioactivity (4.8 mSv) which is below the yearly radiation threshold. Infusion of 18F-FDG can rarely result in treatable side-effects such as an allergic reaction. See the SPC and study protocol for detailed information.

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

- Age between 40 and 80 years
- With or without severe periodontitis with DPSI score of 0-2 resp. 4
- Written informed consent

Exclusion criteria

- Cardiovascular events
- Diabetes mellitus
- Chronic infections other than periodontitis
- Medical history of any disease associated with immune deficiency (either congenital or acquired, including chemotherapy, chronic steroid use, organ transplant)
- Fever (T > 38.5) or antibiotics use for infectious disease within 1 month prior study entry
- Chronic use of anti-inflammatory drugs such as NSAIDs
- Recent hospital admission or surgery with general anaesthesia (< 3 months)
- Known heart failure, chronic kidney (MDRD <45 ml/min) or liver disease (ALAT more than three times upper reference limit or known liver disease)
- Inability to personally provide written informed consent (e.g. for linguistic or mental reasons)
- Inability to undergo PET-CT scanning, including pregnancy

Study design

Design

Study type:	Observational non 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):	15-01-2018
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	10-10-2017
Application type:	First submission
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
Other	clinicaltrails.gov registratienummer volgt
CCMO	NL61840.091.17

Study results

Date completed:	21-02-2019
Actual enrolment:	30