periodontitis increases risk of thrombotic events

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To evaluate wheter patients with parodontitis have a more procoagulant, proinflammatory and metabolically disturbed state than patients with a lower periodontal disease burden. Additionally, we want to explore how this relationship is modified by...

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

Summary

ID

NL-OMON47154

Source
ToetsingOnline

Brief title
PIRATE study

Condition

- Other condition
- Coronary artery disorders
- Embolism and thrombosis

Synonym
gingivitis dental decay

Health condition

parodontitis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Het Mandema-stipendium (onafhankelijke persoonlijke grant van hoofdonderzoeker)

Intervention

Keyword: microbiome, periodontitis, thrombosis

Outcome measures

Primary outcome

Crossectional analysis: difference in coagulation, inflammation and metabolic markers throughout the whole cohort, with PISA as an independent variable

Longitudinal analysis: difference in coagulation, inflammation and metabolic markers of patients before and after undergoing a total tooth extraction

Secondary outcome

Exploratory analysis of the influence of oral mircobiome on the relationships between PISA and primary outcome measures. Our focus will lie in evaluating the quantitative presence of *red complex* bacteria (see Rationale), total bacterial burden and its relationship with PISA and inflammatory/hemostatic status. The goal is to generate hypotheses for further research.

Study description

Background summary

There is growing evidence that a broad range of inflammatory processes are risk factors for both arterial and venous thrombotic events. Periodontitis is a chronic inflammatory process of the gums which arises in response to the accumulation of bacteria in a biofilm on tooth surfaces (dental plaque).

Periodontitis is known to be associated with intermittent bacteraemia originating from oral microbiota and systemic inflammation, e.g. increased CRP levels. Periodontitis has been associated with an increased risk of cardiovascular disease. Although never previously studied, we hypothesize that periodontitis, quantified through the Periodontal Inflammatory Surface Area (PISA) is a risk factor for venous thrombotic events as well. More specifically, we hypothesize that an increasing severity of periodontitis is associated with an increasingly hypercoagulable, proinflammatory and disturbed metabolic state that may predispose to acute thrombotic events.

Study objective

To evaluate wheter patients with parodontitis have a more procoagulant, proinflammatory and metabolically disturbed state than patients with a lower periodontal disease burden. Additionally, we want to explore how this relationship is modified by oral microbiota

Study design

This study has a combined crossectional and longitudinal design:
PIRATE A: cross-sectional study: serum markers for coagulation, inflammation and metabolism parameters, AGEs and oral microbiota of patients referred for extraction of all teeth will be compared to the same measurements randomly selected volunteers. In this analysis, PISA is the main independent variable, and not case vs volunteer.
PIRATE B: cohort study, serum markers for coagulation, inflammation and metabolism parameters and oral microbiota of patients with severe periodontitis will be compared before and after extraction of all teeth, when the PISA is reduced to zero.

Study burden and risks

Patients will be asked questions in relationship to their general health and social-economic status. They will undergo venous blood sampling three times. Before their procedure, a scraping of tongue, and an oral lavage will be collected. For patients undergoing the procedure in general anaesthesia, periodontal status will be acquired during general anaesthesia, just before the surgeon performs the total tooth extraction. Time under general anesthesia will be prolonged for 30 minutes to ascertain PISA measurements and for sampling of Gingival plaque. A final visit ill be required at least 12 weeks after the procedure. At this visit a scraping of tongue, a oral lavage and venous blood will be collected. For measurements of lipids and glucose, they will be requested to fast for this visit. volunteers will be asked to fast for their visit to the UMCG. They wil be asked questions related to their general health and social-economic status. They will undergo venous blood sampling once, after which measurements of PISA will be done. Finally, samples of gingival plaque,

tong scrapings and a oral lavage will be collected.

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

all participants are 18 years or older
cases need an indication to undergo a total tooth extraction. Indication has been made by an oral and maxillofacial surgeon
controls: age, smoking- and educational status matched volunteers who respond to poster advertisements

Exclusion criteria

inability to understand verbal and written Dutch or English language
participants with (end-stage) liver disease (Child Pugh Class A, B and C)
history of chronic auto immune disease (i.e. RA, vasculitis, IBD)
use of antiplatelet or antithrombotic medications
history of radiation in the head/neck region
patients referred for focus detection in order to receive chemotherapy and/or radiotherapy for the treatment of cancer

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):	17-11-2014
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	26-09-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Approved WMO

Date:	07-01-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	26-05-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Not approved Date:	30-03-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	10-04-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	02-07-2018
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	NL49846.042.14