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The effect of treatment of periodontitis on markers of cardiovascular diseases

Submission date	Recruitment status	[_] Prospectively registered
20/08/2013	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
25/09/2013	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
29/01/2019	Oral Health	

Plain English summary of protocol

Background and study aims
There is scientific evidence which supports a relationship between periodontitis (gum disease) and heart disease and metabolic syndrome (MS) (a combination of diabetes, high blood pressure and obesity). There is also proof which shows that standard non-surgical treatment of periodontitis (scaling and root planing) has an effect on markers of heart disease and MS. The main aim of our study is find out whether standard non-surgical treatment has an effect at longer follow-up (12 months) on markers of heart disease and MS. The study also aims to compare four different non-surgical treatment methods of periodontitis in relation to the effect on markers of heart disease and MS.

Who can participate?
Healthy patients, over 19 years old, who are affected by moderate to severe periodontitis who are referred for treatment to the Department of Periodontology of the Academic Centre for Dentistry Amsterdam (ACTA) can participate in the study.

What does the study involve?
Patients are asked to show-up before the start of the treatment at an initial appointment in order to collect some information, blood and saliva samples. At this appointment patients are randomly allocated to one of the four treatment groups: chlorhexidine mouthwash and one of the four antibiotic therapies along with the standard treatment (scaling and root planing). Patients have to bring the medications at the first day of the treatment and the treatment will start under supervision. Four weeks after completion of the treatment, patients are asked to come in for an oral hygiene control. Patients are assessed again at 3 months, 6 months and 12 months after the treatment. At these appointments, clinical information, saliva and blood samples are again collected.

What are the possible benefits and risks of participating?
The patients will mainly benefit from the treatment of periodontitis. The patients who are allocated to the treatment groups with antibiotics may have a greater benefit. The main risks are related to the side effects of the antibiotics and the mouthwash.

Where is the study run from?
The study is run from the Department of Periodontology of the Academic Centre for Dentistry Amsterdam (ACTA), The Netherlands.

When is the study starting and how long is it expected to run for?
The study started in March 2008. We will expect the study to be completed in December 2014.

Who is funding the study?
This study is funded partly by a grant from the University of Amsterdam, The Netherlands.

Who is the main contact?
Mr Sergio Bizzarro, s.bizzarro@acta.nl
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NL19679.018.07

Study information

Scientific Title
The effect of treatment of periodontitis on markers of cardiovascular diseases: a randomized, single blinded, clinical trial

Study objectives
The primary aim of the study is to investigate whether periodontal treatment results in a decrease of plasma biomarkers that are related to cardiovascular diseases and metabolic syndrome.

The secondary aim is to investigate which of the following treatment modalities is the most effective in the reduction of the above mentioned biomarkers: Scaling and root planing; Scaling and root planing + systemic antibiotics (amoxicillin and metronidazole); Scaling and root planing + subgingival disinfection with 0.5% NaOCl; Scaling and root planing + subgingival disinfection with 0.5% NaOCl + systemic antibiotics (amoxicillin and metronidazole).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethics Review Committee (METC); 15/01/2008; Ref: NL19679.018.07
Board Affiliation: Medical Ethics Committee of the Academic Medical Center of Amsterdam, The Netherlands

Study design
Single center randomized single blinded clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Periodontitis, cardiovascular diseases, metabolic syndrome

Interventions
1. Scaling and root planing alone
2. Scaling and root planing + amoxicillin 375mg + metronidazole 250mg
3. Scaling and root planing + subgingival irrigation with 0.5% Natriumhypochlorite
4. Scaling and root planing + amoxicillin 375mg + metronidazole 250 mg + subgingival irrigation 0.5% Natriumhypochlorite

Periodontal treatment is carried out in 3 appointments within one week.
A check up is done 4 weeks after completion of the treatment.
Total follow-up is one year. Assessments are carried out at 3, 6 and 12 months follow-up.

Intervention Type
Other

Phase

Not Applicable

Primary outcome measure
Markers of cardiovascular diseases and metabolic syndrome in peripheral plasma and serum (hsCRP, Lipid profile, hemostatic factors, glucose, insuline, HbA1c). Measured at baseline (before treatment), 3 months, 6 months and 12 months after treatment.

Secondary outcome measures
Clinical (probing pocket depth, bleeding index, plaque index, attachment level) and microbiological parameters of periodontitis. Measured at baseline (before treatment), 3 months, 6 months and 12 months after treatment.

Overall study start date
01/03/2008

Completion date
01/12/2014

Eligibility

Key inclusion criteria
1. Patients both males and females, being 20 years or older
2. Patients affected by periodontitis defined as presence of 1/3 bone loss or more and presence of 6 mm pocket or more, with evidence of attachment loss at 2 or more teeth per quadrant and evidence of generalized bleeding

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
200

Key exclusion criteria
1. No systemic chronic diseases
2. No acute medical interventions or diseases 4 weeks before baseline
3. No pregnancy
4. No chronic medications
5. No antibiotics 6 months before intake and no repeated use of NSAID's medications 4 weeks before intake
6. No hypersensitivity of contraindication for the use of amoxicillin and metronidazole

Date of first enrolment
01/03/2008

Date of final enrolment
01/12/2014

Locations

Countries of recruitment
Netherlands

Study participating centre
Gustav Mahlerlaan 3004
Amsterdam
Netherlands
1081LA

Sponsor information

Organisation
Academic Centre for Dentistry Amsterdam (ACTA), University of Amsterdam and Vrij University of Amsterdam (Netherlands)

Sponsor details
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Sponsor type
University/education

ROR
https://ror.org/04x5wnb75

Funder(s)

Funder type
University/education

Funder Name
This study was self funded by the authors and their Institution. The department of periodontology is funded in part by a grant from the University of Amsterdam for the focal point Oral infection and inflammation.

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2016	29/01/2019	Yes	No
Results article	results	01/08/2017	29/01/2019	Yes	No