

The association between coronary atherosclerosis and periodontitis: A clinical study

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

Summary

ID

NL-OMON40327

Source

ToetsingOnline

Brief title

PaCmAn study: The link between Periodontitis and Coronary Atherosclerosis

Condition

- Other condition
- Coronary artery disorders
- Bacterial infectious disorders

Synonym

atherosclerosis, gum disease

Health condition

parodontale aandoeningen

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

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

Intervention

Keyword: CCS (Coronary Calcium Score), Coronary atherosclerosis, Periodontitis, PISA (periodontal inflamed surface area)

Outcome measures

Primary outcome

Inflammatory burden of periodontal disease will be quantified with the

Periodontal Inflamed Surface Area (PISA) score. The endothelial function will be measured employing *EndoScore* using the ENDOPAT.

Secondary outcome

Reynolds risk score

Framingham risk score

Questionnaires:

- Age
- Sex
- Ethnicity
- Socio-economic status
- Medical history and medication (history)
- Parental history
- Life-style (smoking, alcohol, drugs, stress)
- Oral hygiene

Physical examination:

- Blood Pressure (BP)
- Heart Rate (HR)
- Body Mass Index (BMI)
- Waist to Hip Ratio (WHR)
- Electrocardiogram (ECG)

Biochemical parameters:

- High sensitive C-reactive Protein (hsCRP)
- Total cholesterol
- High Density Lipoprotein (HDL) cholesterol
- Low Density Lipoprotein (LDL) cholesterol
- Triglycerides
- Estimated Glomerular Filtration Rate (eGFR)
- Glycated Hemoglobine (HbA1c)

Extra parameters for coupled studies:

One blood sample for DNA analysis of risk genes for both periodontitis and coronary heart disease.

Oral rinse sample for microbiological analysis of the oral microbiome performed by pyrosequencing of 16S microbial DNA.

Study description

Background summary

Periodontitis is a chronic multi-causal inflammatory disease of the supportive tissues of the teeth with progressive loss of attachment and alveolar bone. Atherosclerosis is perceived today as a chronic inflammatory condition, and infectious diseases are believed to contribute to its pathophysiology. In recent years remarkable pathological and epidemiological relationships between periodontitis and atherosclerosis have been presented. Many previous studies use surrogate biomarkers in order to demonstrate the association between periodontitis and coronary atherosclerosis. Unfortunately, more definitive cardiovascular parameters and endpoints are still lacking.

Study objective

The aim of this study is to determine whether the presence and the extent of periodontitis are independently related to the presence and extent of coronary calcification.

To determine if periodontal treatment has an positive effect on the cardiovascular parameters.

Study design

Follow-up treatment study

Study burden and risks

The radiation exposure of a standard dental panoramic radiograph is estimated to be 0.010 mSv, comparable to 1 day background exposure to the natural radiation in The Netherlands.

Contacts

Public

Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL

Scientific

Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Age 45-70 years

Male and Female

All ethnicities

≥ 10 teeth

Exclusion criteria

Edentulous

Known cardiovascular diseases

Known Diabetes Mellitus

Known autoimmune disorders

Known immunosuppressive disorders

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: Pending

Start date (anticipated): 01-03-2013

Enrollment: 50

Type: Anticipated

Ethics review

Approved WMO

Date: 03-06-2013

Application type: First submission

Review commission: METC Isala Klinieken (Zwolle)

Approved WMO

Date: 04-05-2015

Application type: Amendment

Review commission: METC Isala Klinieken (Zwolle)

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

CCMO

ID

NL43083.075.13