# The effect of treatment of periodontitis on markers of cardiovascular diseases

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Ethical review	Approved WMO
Status	Pending
Health condition type	Myocardial disorders
Study type	Interventional

### Summary

### ID

**NL-OMON32003** 

**Source** ToetsingOnline

Brief title Periodontitis and cardiovascular diseases

### Condition

- Myocardial disorders
- Glucose metabolism disorders (incl diabetes mellitus)
- Bacterial infectious disorders

# **Synonym** cardiovascular diseases, metabolic syndrome

#### **Research involving**

Human

### **Sponsors and support**

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

### Intervention

Keyword: CRP, Inflammation, PAI-1, Periodontitis

### **Outcome measures**

#### **Primary outcome**

Probing pocket depth, bleeding on probing, change in attachment level, level of

subgingival bacterial recolonisation, plasma levels of CRP, PAI-1, fibrinogen,

von Willebrand factor (vWF), Leucocytes, Vitamin C, Insulin and Glucose.

#### Secondary outcome

Proteomes of saliva and serum

# **Study description**

#### **Background summary**

Periodontitis is a destructive inflammation of the supporting tissues (periodontium) of the teeth. Periodontitis is considered a multifactorial infection. Several of the different species of bacteria form the subgingival plaque that can be isolated seem to be strongly associated with periodontitis. It is also important to mention the role played by genetic factors in the etiopathogenesis of the periodontitis. Periodontitis has the tendency to be familiar and there are some gnetic polymorphisms that are associated with the severity of the disease. Besides, lifestyle factors play also an important role. It seems that smoking is the most important, but iet seems to play an important role too. Recent researches show that probably Vitamin C is important. Because of the complex pathogenesis of periodontitis, the understanding about the interaction between the periodontium and the etiologic factors is limited. In this respect, the knowledge of proteomics can be helpful. Epidemiological researches show that there is a possible relationship between periodontitis and the pathogenesis of cardiovascular diseases (CVD) and metabolic syndrome (MS). Different proteins as C-Reactive Protein (CRP), Plasminogen Activator Inhibitor-1 (PAI-1), fibrinogen and von Willebrand Factor (vWF), which can play a role in the prevalence of CVD/MS, are also elevated in periodontitis patients. Recently there are studies published that show that a standard periodontal treatment (scaling, root planning and oral hygiene instructions) in otherwise healthy patients give a reductions in plasma levels of CRP.

At the light of the geographic differences in the prevalence of CVD/MS and periodontitis, as well in dietary habits, education and social class, it is essential to confirm also in the Netherlands that a normal periodontal treatment van lead to a reduction of biomarkers of CVD/MS in otherwise healthy people

### Study objective

1. 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 (CVD) and metabolic syndrome (MS) and what is the effect of the treatment on the proteomic profile in serum.

2. The secundary aim is to investigate which of the following treatment modalities shows the best clinical results and which is the most effective in the reduction of plasma biomarkers related to CVD and MS, and which is the different effect on the proteomic profile:

- SRP (standard periodontal treatment)
- SRP and antibiotics (amoxycillin + metronidazole)
- SRP and subgingival disinfection with 0.5 % NaOCI

- SRP and both antibiotics (amoxycillin + metronidazole) and subgingival disinfection with 0.5 % NaOCl

3. Which of the following variables has a possible influence on the results of the investigation:

- the composition of the subgingival plaque
- Genetic polymorphism for the markers investigated
- lifestyle related factors as smoking and vitamin C

#### Study design

For this project we will submit the first 200 new periodontitis patients that are accepted for treatment at ACTA to a standardized research protocol (unselected cohort).

Every patient will undergo the following:

1) Introduction, explanation of the aim of the research, signing of the inform consent (5 min).

2) General health anamnesis (inclusive blood pressure, weight, length, waist circumference and recording of smoking habits)(15 min).

- 3) Blood sample (10 min).
- 4) Unstimulated saliva sample (5 min).
- 5) Selection of the sites for bacterial sample (4) the deepest pocket per
- quadrant and subsequently subgingival bacterial sampling. (15 min).
- 6) Standard periodontal clinical measurements (bleeding index, probing pocket

depth and clinical attachment level)(50 min).

The patients will be randomly assigned to 4 groups, according to 4 different modalities of treatment: Group A: periodontal treatment (SRP) Group B: SRP with support of antibiotics Group C: SRP with support of NaOCI Group D: SRP with support of antibiotics and NaOCI

2 extra appointments (1 week en 2 weeks after treatment) will be taken for subgingival bacterial sample.

Coded plasma, Serum, DNA of every patient will be saved for the research.

#### Intervention

The patients will be randomly assigned to 4 groups, according to 4 different modalities of treatment: Group A: periodontal treatment (SRP) Group B: SRP with support of antibiotics (amoxycillin 375 mg, 3 per day x 7 days + metronidazole 250 mg, 3 per day x 7 days) Group C: SRP with support of NaOCI (local pocket rinsing) Group D: SRP with support of antibiotics (amoxycillin 375 mg, 3 per day x 7 days + metronidazole 250 mg, 3 per day x 7 days) and NaOCI (local pocket rinsing)

#### Study burden and risks

No other risks than the periodontal treatment and the venepuncture.

# Contacts

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Louwesweg 1 1066 EA, Amsterdam NL

# **Trial sites**

### **Listed location countries**

Netherlands

# **Eligibility criteria**

Age Adults (18-64 years) Elderly (65 years and older)

### **Inclusion criteria**

The patients must show on dental radiograph periodontal bone loss of > 1/3 of the total length of the root on > 1 tooth per quadrant.

### **Exclusion criteria**

- 1) No chronic diseases as CVD or diabetis with exception of periodontitis
- 2) No acute diseases or infections in the last 4 weeks.
- 3) No pregnancy.
- 4) No chronic medications

5) No chronic medications that can have an effect on the periodontal tissues (e.g. antibiotics)

- in the past 6 months and no anti-inflammatory drugs (NSAID's) in the past 4 weeks.
- 6) No hypersensitivity or controindication for the use of amoxycillin and/or metronidazol

# Study design

### Design

Interventional
Parallel
Randomized controlled trial
Single blinded (masking used)
Active

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-10-2007
Enrollment:	200
Туре:	Anticipated

### Medical products/devices used

Product type:	Medicine
Brand name:	amoxycillin 375mg
Generic name:	broad-spectrum penicillin
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	motronidazole 250mg
Generic name:	antibiotics
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	natrium hypochlorite
Generic name:	medication for woundhealing and skin disinfection

# **Ethics review**

Approved WMO	
Date:	10-12-2007
Application type:	First submission
Review commission:	METC Amsterdam UMC

# **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
EudraCT	EUCTR2007-004405-95-NL
ССМО	NL19679.018.07