The effect of treatment of periodontitis on markers of cardiovascular diseases

Published: 28-06-2007
Last updated: 08-05-2024

The aim of the research is to enroll 100 consecutive untreated periodontitis patients for the normal standard treatment. We will investigate by means of venous blood analyses before treatment and 3, 6, and 12 months after treatement whether plasma…

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

Summary

ID

NL-OMON30481

Source
ToetsingOnline

Brief title
Periodontitis and cardiovascular diseases

Condition

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

Synonym
cardiovascular diseases, metabol 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, 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

The aim of the research is to enroll 100 consecutive untreated periodontitis patients for the normal standard treatment. We will investigate by means of venous blood analyses before treatment and 3, 6, and 12 months after treatement whether plasma levels of biomarkers related to CVD/MS are reduced after treatment. Levels of these biomarkers will be related also to the microbial composition of the infection and the genetic polymorphisms and lifestyle factors.

Study design

De totale tijdsduur voor de patiënt bij de eerste afspraak is 1,5 uur.
Vervolgens zullen punten 2 t/m 5 herhaald worden tijdens de normale bezoeken op 3, 6 en 12 maanden na het afronding van de behandeling (4ma, 7ma en 13ma).
Klinische metingen worden standaard uitgevoerd op deze bezoeken en zullen t.b.v. het onderzoek overgenomen worden uit het dossier van de patiënt.

Van iedere patient zal -gecodeerd- plasma, serum en DNA worden opgeslagen voor het onderzoek.

For this project we will submit the first 100 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 total time needed at the first appointment will be of 1,5 hour. The points 2-5 will be repeated during the normal maintenance appointments 3, 6 and 12

months after the accomplishment of the treatment. The periodontal clinical measurements will be carried out during the maintenance visits. They will be consulted in the patient chart on behalf of the research.

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

Intervention

Standard periodontal treatment (oral hygiene instructions, mechanical scaling and root planing)

Study burden and risks

No other risks than the standard periodontal treatment and the venepuncture.

Contacts

Public
Universiteit van Amsterdam

Louwesweg 1
1066 EA, Amsterdam
Nederland
Scientific
Universiteit van Amsterdam

Louwesweg 1
1066 EA, Amsterdam
Nederland

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 pregnancy.
2) No chronic diseases with exception of periodontitis and no acute diseases or infections in the last 4 weeks.
3) No chronic medications
4) 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.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2007
Enrollment:	100
Type:	Anticipated

Ethics review

Approved WMO

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
CCMO	NL15199.018.07