Periodontitis as a potential early risk indicator for diabetes mellitus, atherosclerotic cardiovascular disease, metabolic syndrome and obstructive sleep apnea syndrome

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The aim of the proposed study is to screen for (pre)DM, an increased 10-year-risk of ASCVD, MetS and a high risk of OSAS in subjects with and without periodontitis. Consequently, the dental office will be evaluated as a suitable location for early...

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

Summary

ID

NL-OMON48894

Source ToetsingOnline

Brief title Periodontitis as signal for an underlying disease

Condition

- Other condition
- Cardiac disorders, signs and symptoms NEC
- Glucose metabolism disorders (incl diabetes mellitus)

Synonym

Cardiovascular disease, Diabetes, Metabolic Syndrome, Obstructive Sleep Apnea Syndrome, Periodontitis

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Health condition

orale aandoeningen

Research involving Human

Sponsors and support

Primary sponsor: Vrije Universiteit

Source(s) of monetary or material Support: Ministerie van OC&W,Topconsortium Kennis en Innovatie (TKI)-toeslag;Rijksdienst voor ondernemend nederland;onderdeel van ministerie van Economische Zaken,Labonovum BV (in kind),Sunstar Suisse SA (cash en in kind),Sunstar Suisse SA (cash en in kind);Labonovum B.V. (in kind)

Intervention

Keyword: Cardiovascular disease, Diabetes Mellitus, Periodontitis, Screening

Outcome measures

Primary outcome

To investigate, within a dental setting, the differences between periodontitis

and non-periodontitis patients in:

- The prevalence of preDM and DM
- The *10-year-risk* of ASCVD
- The prevalence of MetS
- The risk of OSAS (low, intermediate, high)

Secondary outcome

Secondary Objectives (cross-sectional):

- To investigate the differences in (pre)DM prevalence, 10-year-risk of ASCVD,

MetS prevalence and OSAS risk between non, mild/moderate and severe

periodontitis patients

- To measure qualitatively and quantitatively in a mouth rinse the same

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biochemical markers as in the venipuncture/finger stick procedure
To study the oral microbiome in a mouth rinse in relation to pre-DM, DM,
10-year-risk of ASCVD, MetS and OSAS between non, mild/moderate and severe
periodontitis patients

Secondary Objective(s) (longitudinal):

- To evaluate whether patients visited their primary care physician based on

the outcomes of the above mentioned screening for preDM, DM, 10-year-risk of

ASCVD, MetS and OSAS

- To explore the changes of biochemical markers over time in blood and oral

rinse samples of periodontitis patients who underwent standard treatment of

care in the clinics of ACTA

- To study the oral microbiome in a mouth rinse in relation to pre-DM, DM,

10-year-risk of ASCVD and MetS in periodontitis patients who underwent standard

treatment of care in the clinics of ACTA

Study description

Background summary

Diabetes Mellitus (DM), Atherosclerotic Cardiovascular Disease (ASCVD), Metabolic Syndrome (MetS) and Obstructive Sleep Apnea Syndrome (OSAS) are major health problems. However due to absence of symptoms and/or lack of knowledge, people are often unaware of having DM, ASCVD, MetS or OSAS while early treatment could prevent or stop the progression of these diseases. Therefore risk indicators for early detection of DM, ASCVD, MetS and OSAS are needed and proposed.

Many studies demonstrate the association between oral diseases and DM and/or ASCVD. The most observed chronic oral disease is periodontitis. Periodontitis

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is a common chronic multifactorial inflammatory disease of the supporting structures of the teeth. DM and ASCVD might, due to their pro-inflammatory state and alteration of the immune system, contribute to the onset and/or progression of periodontitis. Therefore periodontitis could be considered as an early sign of an underlying vascular and/or metabolic pathology.

Some studies have also reported a positive association between periodontitis and MetS. The MetS prevalence in patients with periodontitis was shown to be higher than controls and MetS showed to be associated with severe periodontitis. The association between periodontitis and OSAS is less established, however there is some evidence to a plausible association between periodontal disease and Obstructive Sleep Apnea (OSA).

Due to the broad overlap of objective biomarkers, in this study, subjects with or without periodontitis will be screened for determining the prevalence of (pre)DM, the 10-year-risk of ASCVD, the prevalence of MetS and the risk of OSAS. The screening will be based on clinical measures, specific blood markers determined by venipuncture or finger stick procedure and two questionnaires.

Notably, a recently published pilot paper from our research group presents the feasibility and preliminary results of proposed screening for (pre)DM; we found 18.1% new DM cases among subjects with severe periodontitis compared to 9.9% in mild/moderate periodontitis and 8.5% in controls.

Besides blood, also a 30 seconds mouth rinse can be used to measure for DM, ASCVD and MetS biomarkers in patients with periodontitis and controls. Because the majority of dental offices may not be keen on applying the finger stick, the use of biochemical markers in a simple, non-invasive, rapid (30-sec) mouth rinse may be an alternative and feasible approach for screening of biochemical markers during a dental visit.

From the same mouth rinse also the oral microbiome can be assessed. The microbial composition in various ecological niches of the body is now regarded indicative for the functioning of the individual*s health. If the oral microbiome reflects a disease pattern or *finger print*, it can be very useful to make a distinction between normal and diseased oral microbiomes. The focus of our study is the early detection of DM and ASCVD, and therefore, also knowledge about the oral microbiome relatively simple from the mouth rinse and we will correlate this to clinical and biochemical measurements. New knowledge obtained will help in designing further steps to obtain a normal and functional oral microbiome in relation to the important systemic diseases such as DM, ASCVD and MetS.

After screening for above mentioned diseases, the periodontitis patients will be approached again during a follow-up to investigate whether they indeed visited their general practitioner if they were advised to do so. Also we will explore the variation in periodontal treatment outcomes and whether or not these are affected by the obtained patterns of biochemical markers (from blood analyses and oral rinse samples) and oral microbiome signatures (from oral rinse samples).

Study objective

The aim of the proposed study is to screen for (pre)DM, an increased 10-year-risk of ASCVD, MetS and a high risk of OSAS in subjects with and without periodontitis. Consequently, the dental office will be evaluated as a suitable location for early detection of these diseases.

Study design

Cross-sectional and follow-up study

Study burden and risks

- The extra burden for the patients and control subjects will be two questionnaires, measurement of blood pressure, weight, waist and neck circumference, venipuncture or finger stick procedure and an oral rinse of 30 seconds.

- The risks associated with participation are negligible.

- Possible benefit of participation will be early detection of health risks such as (pre)DM, ASCVD, MetS, OSAS and possibly a referral for further diagnosis and/or treatment at the family physician.

Contacts

Public Vrije Universiteit

Gustav Mahlerlaan 3004 Amsterdam 1081 LA NL **Scientific** Vrije Universiteit

Gustav Mahlerlaan 3004 Amsterdam 1081 LA NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

- Age * 40 years
- (Patient) referred for periodontitis

- (Control) visiting the dental school for regular dental check-up without periodontitis - Able and willing to give written informed consent and comply with the requirements of the study protocol.

Exclusion criteria

None

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	25-02-2018
Enrollment:	783
Туре:	Anticipated

Ethics review

Approved WMO	
Date:	22-02-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	08-02-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	11-04-2019
Application type:	Amendment
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 ClinicalTrials.gov CCMO

ID NCT03459638 NL62337.029.17