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Can dental treatment protect us from heart disease?

Submission date	Recruitment status	[_] Prospectively registered
10/01/2018	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/01/2018	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
27/02/2023	Oral Health	

Plain English summary of protocol

Background and study aims
Platelets are small blood cells that aggregate (bind) upon activation, which can cause thrombus formation and activation of the immune system. Thereby platelet activation leads to the initiation and progression of cardiovascular disease. As platelets are very sensitive even mild inflammatory stimuli can activate them. Recently we found that periodontitis (gum disease), a chronic inflammation of the gums and areas around the death, results in platelet activation. Periodontal disease has previously been associated with cardiovascular disease and platelet activation provides an important link. Therefore, the aim of this study is to investigate if periodontal treatment, the cleaning of the dental pockets to diminish inflammation, can prevent platelet activation.

Who can participate?
Adults aged 18 and older who have periodontal disease.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive the periodontal treatment at the beginning of the study and provide blood samples before and after three months of treatment. Those in the second group are simple informed about dental hygiene and receive their treatment three months later after the study has finished.

What are the possible benefits and risks of participating?
Participants may benefit from the periodontal treatment for systemic disease like cardiovascular disease. As only little amounts of blood are needed the study bears no medical risk for the patients. Postponing periodontal treatment for 3 months, e.g. in the control group, should not put patients at risk either. In case they are in pain or suffer from any other dental complications, they will be excluded from the study and receive full dental treatment. Further we provide financial reimbursement for study participants.

Where is the study run from?
Medical University of Vienna (Austria)

When is the study starting and how long is it expected to run for?
October 2015 to October 2018

Who is funding the study?
Medical Scientific Fund of the Mayor of the City of Vienna (Austra)

Who is the main contact?
Professor Alice Assinger (Scientific)

Contact information

Type(s)
Scientific

Contact name
Prof Alice Assinger

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PAROII/2016

Study information

Scientific Title
Does periodontal treatment prevent platelet activation in patients with periodontitis? A controlled therapeutic trial

Acronym
TreatPP

Study objectives
Immediately after treatment, platelet activation would be increased, while patients might gain long-term (cardio)vascular benefits from the periodontal treatment. The results of this study are

supposed to add significant knowledge to a comprehensive view of the systemic consequences of periodontal disease.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical commission of the Medical University of Vienna, 02/09/2014, ref: 1656/2014

Study design
Randomised controlled intervention trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Periodontitis

Interventions
Eligible patients undergo baseline anamnesis of periodontal disease, microbiological assessment (PCR, 11 putative periodontal pathogens) and blood testing and full medical and dental histories were collected. Then patients are randomly assigned to receive intensive periodontal treatment (treatment group) or community-based periodontal care (control group).

Patients of the control group receive community based periodontal care. Their intensive periodontal takes place three months after diagnosis, i.e. after their study participation.

Intensive periodontal treatment is performed by subgingival debridement with curettes and sonic instruments generally in two to four treatment sessions after the initial examination. Each session of subgingival debridement lasted for 1-2 hours with an interval of one week between treatment appointments. At the beginning of each appointment a simplified plaque score is recorded and appropriate individualized oral hygiene instructions are given.

Intervention Type
Procedure/Surgery

Primary outcome measure

Platelet P-selectin surface expression is measured using whole blood from patients and laboratory analysis via flow cytometry before and immediately after treatment and 3 months after.

Secondary outcome measures
Platelet aggregation is measured using whole blood from patients and laboratory analysis via light transmission aggregometry before and immediately after treatment and 3 months after.

Overall study start date
01/10/2015

Completion date
01/10/2018

Eligibility

Key inclusion criteria
1. Understanding of the study requirements
2. At least one interproximal site with a probing depth ≥ 5 mm and a loss of attachment at ≥ 2 interproximal sites ≥ 5 mm
3. Ages 18 and older

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100

Total final enrolment
52

Key exclusion criteria
1. Systemic diseases including diabetes mellitus
2. Chronic renal failure or liver cirrhosis
3. Systemic antibiotic treatment in the preceding 3 months
4. Periodontal treatment within the last 4 months
5. Pregnancy or breast feeding
6. Medication which affects platelets

Date of first enrolment

01/11/2015

Date of final enrolment
01/06/2016

Locations

Countries of recruitment
Austria

Study participating centre
Medical University of Vienna
Division of Conservative Dentistry and Periodontology
School of Dentistry
Vienna
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Sponsor information

Organisation
Anniversary Fund of the Austrian National Bank

Sponsor details
Otto Wagner Platz 3
Vienna
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Sponsor type
Government

ROR
https://ror.org/00nkcmy90

Funder(s)

Funder type
Charity

Funder Name
Medical Scientific Fund of the Mayor of the City of Vienna

Funder Name
Austrian Science Fund (FWF P-24978)

Funder Name
Anniversary Fund of the Austrian National Bank (OeNB grant#15961)

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal within 2 years of study end date.

Intention to publish date
01/10/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from markus.laky@meduniwien.ac.at

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		12/01/2018	01/04/2019	No	Yes
Results article	results	01/09/2018	23/11/2020	Yes	No
Results article		29/08/2019	27/02/2023	Yes	No