ISRCTN13626790 https://doi.org/10.1186/ISRCTN13626790

The impact of gum disease on the levels of a cardiovascular disease marker in the body

Submission date
21/06/2022

Recruitment status
No longer recruiting

Registration date
08/07/2022

Overall study status
Completed

Last Edited
16/01/2023

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The endothelium is a thin membrane that lines the inside of the heart and blood vessels. Endothelial dysfunction is one of the early events in atherosclerosis (the thickening or hardening of the heart arteries). Severe gum disease (periodontitis) is considered to be a contributing risk factor for endothelial dysfunction. High blood concentration of a marker protein called asymmetric dimethylarginine (ADMA), has emerged as a predictor of the risk of cardiovascular disease. Thus, reducing periodontal inflammation might have clinical relevance in cardiovascular disease. Insufficient clinical evidence exists to draw clear conclusions regarding the long-term effects of periodontal disease on endothelial function, and even less evidence is available on ADMA concentration and its relationship with periodontitis. The aim of this study was to evaluate the effects of intensive periodontal treatment in modulating endothelial function via the assessment of plasma ADMA concentration in patients diagnosed with severe periodontitis.

Who can participate?
Adult patients diagnosed with generalized periodontitis

What does the study involve?
In this 6-month study, all patients will undergo a complete medical and clinical periodontal examination, laboratory analysis of ADMA, and ultrasound assessment of fibromuscular dysplasia (FMD) of the right brachial artery. After the screening, patients were randomly assigned to receive Intensive Periodontal Treatment or Community-based Periodontal Care. A full examination was carried out at baseline, 3 and 6 months after periodontal treatment.

What are the possible benefits and risks of participating?
There are no risks of participating. Benefits are related to the potential improvement of cardiovascular markers.

Where is the study run from?
University of Bari Aldo Moro (Italy)

When is the study starting and how long is it expected to run for?
July 2017 to October 2019

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Biagio Rapone (Italy)
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Contact information

Type(s)
Principal Investigator

Contact name
Dr Biagio Rapone

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
The impact of periodontal inflammation on endothelial function assessed by circulating levels of asymmetric dimethylarginine: a single-blinded randomized clinical trial

Acronym
P.I.ADMA

Study objectives
Periodontal treatment reduces the concentrations of asymmetric dimethylarginine in patients with a high risk of endothelial dysfunction

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 16/01/2018, Albania University Ethics Committee (Albanian University, Rr 'Durresit", Tirane 1001, Albania; +355 (0)686086880; e.quorri@albanianuniversity.edu.al), ref: Nr. 16

Study design
Single-center single-blinded randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Generalized periodontitis with no risk for endothelial dysfunction

Interventions
This was a 6-month, randomized controlled trial, including 140 patients between 41 and 63 years old, diagnosed with severe periodontitis, free from cardiovascular disease (CVD), and traditional cardiovascular risk factors. All patients underwent complete medical and clinical periodontal examination, laboratory analysis of ADMA, and ultrasound assessment of fibromuscular dysplasia (FMD) of the right brachial artery. After the screening, they were randomly assigned to receive intensive periodontal treatment (test group, n = 70) or community-based periodontal care (control group, n = 70). A full examination was carried out at baseline, 3 and 6 months after periodontal treatment.

Intervention Type
Procedure/Surgery

Primary outcome measure
Asymmetric dimethylarginine levels in blood measured by enzyme-linked immunosorbent assay (ELISA, DLD Diagnostika, Hamburg, Germany) at baseline, 3 and 6 months

Secondary outcome measures
1. Fibromuscular dysplasia (FMD) of the right brachial artery measured using ultrasound at baseline, 3 and 6 months
2. Periodontal indices using a periodontal probe at baseline, 3 and 6 months

Overall study start date
03/07/2017

Completion date
10/10/2019

Eligibility

Key inclusion criteria
1. Aged between 41 years old and 63 years old
2. Diagnosis of generalized periodontitis

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
70 patients per group

Total final enrolment
140

Key exclusion criteria
1. Patients presenting with dental implants, orthodontic bands and ulcers
2. Patients who received periodontal treatment within 12 months prior to the start of the study
3. Patients who received systemic antibiotics within the last 6 months
4. Pregnancy or breastfeeding mothers
5. History of diabetes or a fasting glucose level greater than 126 mg/dl
6. History of cardiovascular disease
7. Patients with any systemic disease:
7.1. Diabetes mellitus
7.2. Cardiovascular disease
7.3. Kidney disease
7.4. Liver disease
7.5. Lung disease
8. Patients with cardiovascular risk factors and active smokers were excluded to minimize any confounding effect of conditions that may influence endothelial function

Date of first enrolment
06/06/2018

Date of final enrolment
07/12/2018

Locations

Countries of recruitment
Albania

Study participating centre
Albania University
Rr "Durrèsit", Tiranè 1001
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Sponsor information

Organisation
University of Bari Aldo Moro

Sponsor details
Piazza Giulio Cesare 11
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Sponsor type
University/education

Website
http://www.uniba.it/english-version

ROR
https://ror.org/027ynra39

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
31/07/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to the risk of improper use.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	18/07/2022	16/01/2023	Yes	No