

The effect of treatment for gum disease (periodontitis) on the type and amount of lipids (fats) in the blood and the function of the endothelium, the thin membrane that lines the heart and blood vessels, in patients with type 2 diabetes

Submission date 18/07/2022	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 23/07/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 16/01/2023	Condition category Oral Health	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

The aim of this study is to investigate whether treating gum disease (generalized periodontitis) in patients diagnosed with type 2 diabetes is able to change the level and type of fats (lipid) in the blood, termed the lipid profile, and the function of the endothelium, the thin membrane that lines the heart and blood vessels.

Who can participate?

Patients diagnosed with type 2 diabetes with gum disease (generalized periodontitis)

What does the study involve?

What are the possible benefits and risks of participating?

The possible benefit of participating in the trial is the improvement of lipid profile and endothelial function. There are no risks associated with participation in the trial.

Where is the study run from?

Albanian University (Albania)

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

January 2018 to March 2019

Who is funding the study?

Investigator initiated and funded

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

Type(s)

Principal investigator

Contact name

Dr Biagio Rapone

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

Nil known

Study information

Scientific Title

The impact of intensive periodontal treatment on lipid profile and endothelial function in patients with type 2 diabetes: A randomized clinical trial

Study objectives

Intensive periodontal therapy improves the serum lipid profile and the endothelial function in patients with type 2 diabetes

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 27/03/2018, Albanian University Committee (Albanian University, Rruga e Durrësit, Tirane I 001, Albania; +355 686086880; e.qorri@albanianuniversity.edu.al), ref: Nr.114

Study design

Randomized controlled clinical trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Improvement of endothelial function and serum lipid profile in patients with type 2 diabetes via periodontal treatment

Interventions

Before treatment, patients of both groups received oral hygiene instructions. All study participants underwent Intensive Periodontal Treatment (IPT) or Control Periodontal Treatment (CPT) within 1 month from the baseline visit. The protocol of IPT consisted of a single session of one-stage full-mouth disinfection (OSFM), which implicated, supra- and sub-gingival mechanical debridement scaling and manual root surface and calculus removal of all pockets, under local analgesia, within 24 hours in association with chlorhexidine application to all oropharyngeal niches (chairside and at home for 2 months after treatment). Additionally, periodontal surgery was executed for periodontal pockets >5 mm or residual periodontal pockets. The CPT included supra-gingival mechanical debridement. The root planning was delayed at 6 months, after the completion of the trial. At 3 months, supra- and sub-gingival mechanical debridement scaling was executed for both groups.

Intervention Type

Procedure/Surgery

Primary outcome(s)

Serum lipid profile including levels of:

1. Serum total cholesterol measured by enzyme-linked immunosorbent assays (ELISA) at baseline, 3, and 6 months
2. Serum triglyceride measured by ELISA at baseline, 3, and 6 months
3. Low-density lipoprotein cholesterol measured by ELISA at baseline, 3, and 6 months
4. High-density lipoprotein cholesterol measured by ELISA at baseline, 3, and 6 months
5. Flow-mediated vasodilation (FMD) was assessed non-invasively, using the flow-mediated dilation (FMD) technique at baseline, 3, and 6 months
- as an index of endothelium-dependent vasodilation

Key secondary outcome(s)

1. High-sensitive C-reactive protein measured using a commercially available kit at baseline, 3, and 6 months
2. Periodontal pocket depth measured using the manual periodontal probe at baseline, 3, and 6 months
3. Clinical attachment level measured using the manual periodontal probe at baseline, 3, and 6 months

Completion date

29/03/2019

Eligibility

Key inclusion criteria

1. Patients diagnosed with type 2 diabetes
2. Generalized periodontitis

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

290

Key exclusion criteria

1. Provision of informed consent prior to initiation of any study procedures
2. Declined cognitive function and unable to make informed consent
3. Periodontal treatment within the last 12 months
4. Systemic antibiotic therapy within the last 6 months
5. Pregnancy or breastfeeding
6. Uncontrolled hypertension
7. History of heart disease or stroke which might interfere with systemic antioxidative status
8. Active smokers (>10 cigarettes/daily) were excluded

Date of first enrolment

28/03/2018

Date of final enrolment

23/05/2018

Locations

Countries of recruitment

Albania

Study participating centre

Faculty of Medical Sciences, Albanian University

Bulevardi Zogu I

Tirane

Albania

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Sponsor information

Organisation

Albanian University

ROR

<https://ror.org/02f8a6404>

Funder(s)

Funder type

Other

Funder Name

Investigator-initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available

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	09/10/2022	16/01/2023	Yes	No