ISRCTN69139365 https://doi.org/10.1186/ISRCTN69139365

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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/07/2022	**Overall study status** Completed	
Last Edited 16/01/2023	**Condition category** Oral Health	

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. The 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)
biagio.rapone@uniba.it

Contact information

Type(s)
Principal investigator

Contact name
Dr Biagio Rapone

Contact details
University of Bari Aldo Moro
Piazza Giulio Cesare 11
Bari
Italy
70124
+3477619817
biagio.rapone@uniba.it

Additional identifiers

Clinical Trials Information System (CTIS)
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 Universit, Rruga e Durresit, 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
1001

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