

# 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

<b>Submission date</b> 18/07/2022	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 23/07/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 16/01/2023	<b>Condition category</b> 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)  
biagio.rapone@uniba.it

## Contact information

### Type(s)

Principal Investigator

### Contact name

Dr Biagio Rapone

### Contact details

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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 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)

## **Study design**

Randomized controlled clinical trial

## **Primary study design**

Interventional

## **Secondary study design**

Randomised controlled trial

## **Study setting(s)**

Other

## **Study type(s)**

Treatment

## **Participant information sheet**

No participant information sheet available

## **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 measure**

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

### **Secondary outcome measures**

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

### **Overall study start date**

02/01/2018

### **Completion date**

29/03/2019

## **Eligibility**

### **Key inclusion criteria**

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

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Sex**

Both

### **Target number of participants**

145 per group

### **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

**Sponsor details**

Rruga e Durrësit

Tirana

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**Sponsor type**

University/education

**Website**

<https://albanianuniversity.edu.al>

**ROR**

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

## **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**

20/08/2022

**Individual participant data (IPD) sharing plan**

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

**IPD sharing plan summary**

Not expected to be made available

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	09/10/2022	16/01/2023	Yes	No