

# The effect of treatment for gum disease (periodontitis) plus ozone gas therapy on 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> 05/08/2025	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

The theory of there being a relationship between inflammatory gum disease (periodontitis) and diabetes explains the variations in glycaemic control in patients with diabetes after periodontal treatment. Likewise, the presence of oxidative stress, a common trigger in the onset of both diseases, had led to the understanding of periodontitis as a risk factor in the progression of diabetes. Ozone therapy, in addition to periodontal treatment, has been demonstrated to be effective in reducing systemic oxidative stress.

### Who can participate?

Patients with type 2 diabetes mellitus (T2DM) and generalized periodontitis

### What does the study involve?

Subjects will receive either periodontal treatment followed by up to 6 sessions of gaseous ozone therapy or periodontal therapy alone

### What are the possible benefits and risks of participating?

The benefit of treatment is an improvement of oxidative status. There are no risks associated with participation in the study.

### Where is the study run from?

Albanian University (Albania)

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

May 2018 to May 2019

### Who is funding the study?

Investigator initiated and funded

Who is the main contact?  
Dr Biagio Rapone (Albania)  
biagiorapone79@gmail.com

## 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 effect of gaseous ozone therapy in addition to periodontal treatment on oxidative stress in individuals with type 2 diabetes: A double-blinded, randomized clinical trial

### Study objectives

Periodontal treatment plus gaseous ozone therapy reduces oxidative stress in type 2 diabetes patients more than periodontal treatment alone

### Ethics approval required

Old ethics approval format

**Ethics approval(s)**

Approved 16/07/2018, Albanian University Committee (Rruga e Durrësit, Tiranë | 001 Albania; +355 686086880; e.qorri@albanianuniversity.edu.al), ref: 224

**Study design**

Double-blinded 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**

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

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

Reduction of oxidative stress in patients with type 2 diabetes via periodontal treatment and ozone therapy

**Interventions**

Subjects receive either periodontal treatment followed by up to 6 sessions of gaseous ozone therapy or periodontal therapy alone

**Intervention Type**

Device

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

Gaseous ozone

**Primary outcome measure**

Oxidative stress quantified as the total oxidant status (TOS), total antioxidant status (TAS), nitric oxide (NO) levels, malondialdehyde (MDA) levels, glutathione (L-γ-glutamyl-L-cysteinyl-glycine, GSH) levels measured using a commercially available kit to derive in saliva and a spectrophotometric procedure in blood at baseline, 3, and 6 months

**Secondary outcome measures**

1. Periodontal depth (PD) measured using a periodontal probe at baseline, 3, and 6 months
2. Clinical attachment level (CAL) measured using a periodontal treatment at baseline, 3, and 6 months
3. Bleeding on Probing (BOP) measured using a periodontal probe at baseline, 3 and 6 months

**Overall study start date**

10/05/2018

**Completion date**

17/05/2019

## Eligibility

**Key inclusion criteria**

1. Meet the type 2 diabetes mellitus (T2DM) diagnostic criteria recommended by the American Diabetes Association (ADA) in 2020:
  - 1.1. FPG  $\geq 126$  mg/dl (7.0 mmol/l), or 2-h PG  $\geq 200$  mg/dl (11.1 mmol/l) during OGTT, or HbA1C  $\geq 6.5$  % (48 mmol/mol), or a random plasma glucose  $\geq 200$  mg/dl (11.1 mmol/l)
2. Diagnosis of generalized periodontitis

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

100 patients per group

**Total final enrolment**

200

**Key exclusion criteria**

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

**Date of first enrolment**

20/07/2018

**Date of final enrolment**

13/09/2018

# Locations

## Countries of recruitment

Albania

## Study participating centre

Faculty of Medical Sciences, Albanian University

Rruga e Durrësit

Tirane

Albania

001

# Sponsor information

## Organisation

Albanian University

## Sponsor details

Rruga e Durrësit

Tirana

Albania

001

+355 686086880

informacioni@albanianuniversity.edu.al

## 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

18/08/2022

## 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>		16/01/2022	13/01/2023	Yes	No
<a href="#">Results article</a>		11/05/2023	15/05/2023	Yes	No
<a href="#">Results article</a>		05/09/2024	05/08/2025	Yes	No