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The effect of treatment for gum disease (periodontitis) plus ozone gas therapy on patients with type 2 diabetes

Submission date
18/07/2022

Recruitment status
No longer recruiting

Registration date
23/07/2022

Overall study status
Completed

Last Edited
05/08/2025

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 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)
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Contact information

Type(s)
Principal investigator

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
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 Durresit, Tirane I 001 Albania; +355 686086880; e.qorri@albanianuniversity.edu.al), ref: 224

Study design

Double-blinded randomized controlled clinical trial

Primary study design
Interventional

Study type(s)
Treatment

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(s)
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

Key secondary outcome(s))
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

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 ≥126 mg/dl (7.0 mmol/l), or 2-h PG ≥200 mg/dl (11.1 mmol/l) during OGTT, or HbA1C ≥6.5 % (48 mmol/mol), or a random plasma glucose ≥200 mg/dl (11.1 mmol/l)
2. Diagnosis of generalized periodontitis

Participant type(s)

Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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 Medicai Sciences, Albanian University
Rruga e Durresit
Tirane
Albania
001

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		16/01/2022	13/01/2023	Yes	No
Results article		11/05/2023	15/05/2023	Yes	No
Results article		05/09/2024	05/08/2025	Yes	No