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How gum treatment may help improve blood sugar control in people with type 2 diabetes

Submission date
14/01/2026

Recruitment status
No longer recruiting

Registration date
20/01/2026

Overall study status
Completed

Last Edited
10/11/2026

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Periodontal disease and type 2 diabetes mellitus (T2DM) are two highly prevalent chronic conditions that share common inflammatory and metabolic pathways. Scientific evidence has demonstrated a bidirectional relationship between these conditions, whereby poor glycaemic control may exacerbate periodontal inflammation, and periodontal infection may negatively influence systemic metabolic control. The aim of the present randomized controlled clinical study is to evaluate the effect of non-surgical periodontal therapy on metabolic parameters in patients diagnosed with T2DM. Specifically, the study aims to determine whether improvements in periodontal status result in measurable changes in glycaemic control and systemic inflammatory markers over a 6-month follow-up period.

Who can participate?
Adults aged between 18 and 70 years diagnosed with type 2 diabetes mellitus and presenting with periodontitis are eligible to participate. Participants must have a minimum of 10 natural teeth (excluding third molars) and meet the predefined periodontal and metabolic inclusion criteria.
Individuals are excluded if they have received recent periodontal therapy or antibiotics lately, present with systemic conditions that may interfere with periodontal healing, are pregnant or breastfeeding, or are unable to attend scheduled follow-up visits.

What does the study involve?
Participants enrolled in the study undergo an initial clinical and laboratory assessment at baseline, followed by follow-up evaluations at 3 and 6 months. After baseline assessment, participants are randomly assigned to one of two parallel groups: (a) A control group, receiving standardized oral hygiene instructions and motivation, (b) A treatment group, receiving non-surgical periodontal therapy in addition to oral hygiene instructions. At each visit, periodontal clinical parameters and laboratory measurements related to glycaemic control and systemic inflammation are recorded. All procedures are conducted according to standardized clinical protocols by a calibrated examiner.

What are the possible benefits and risks of participating?
Participants may benefit from comprehensive periodontal evaluation, close clinical monitoring,

and, for those in the treatment group, active periodontal therapy. Participants in the control group are offered periodontal treatment at the conclusion of the study period.
The risks associated with participation are minimal and primarily related to routine periodontal procedures, such as temporary discomfort, dentinal hypersensitivity, or mild gingival inflammation. No experimental drugs or invasive medical procedures are involved.

Where is the study run from?
University of Medicine Tirana (Albania)

When is the study starting and how long is it expected to run for?
Participant recruitment began in June 2024. Follow-up assessments are conducted over a 6-month period for each participant. Data collection is expected to be completed in March 2026, in accordance with the predefined study protocol.

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Besian Abazi, abazi.besian@gmail.com

Contact information

Type(s)
Principal investigator, Scientific, Public

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Study information

Scientific Title
Effect of non-surgical periodontal therapy on diabetes mellitus

Study objectives
The primary objective of this study is to evaluate the effect of non-surgical periodontal therapy on glycaemic control in patients with type 2 diabetes mellitus, as measured by changes in HbA1c over a 6-month period.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 22/02/2024, Council of Ethics of the University of Medicine of Tirana (Rr.e Dibres, Tirana, 1000, Albania; -; info@umed.edu.al), ref: Vendimi nr.8, 22.02.2024

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Prevention, Screening, Treatment

Study type(s)

Health condition(s) or problem(s) studied
Whether non-surgical periodontal therapy can improve glycemic control and systemic inflammation in patients with type 2 diabetes mellitus by reducing periodontal inflammation.

Interventions
Current interventions, as of 10/11/2026:

Clinical procedures and intervention group
The study involved two parallel groups, with assessments at baseline and at 3 and 6 months. All periodontal examinations and treatments were carried out by the principal investigator at the same clinical site, following a standardised protocol. Blood samples and periodontal measurements were obtained before any treatment or reinstrumentation scheduled for that visit. Participants in the intervention group received full-mouth non-surgical periodontal therapy in one session, using ultrasonic instrumentation and Gracey curettes under local anaesthesia, together with standardised oral hygiene instructions. At the 3- and 6-month visits, participants underwent periodontal reassessment. Sites with persistent bleeding on probing and/or residual periodontal pockets received subgingival reinstrumentation as clinically indicated. Oral hygiene instructions were reinforced at each visit.

Control group
Control participants received standardised oral hygiene instructions at baseline and at the 3- and 6-month visits. Instructions covered toothbrushing, interdental cleaning with dental floss, plaque control, and motivation to maintain oral hygiene at least twice daily. During the six-

month observation period, control participants received no subgingival instrumentation, scaling and root planing, or other professional periodontal treatment. Non-surgical periodontal therapy was offered after completion of the final six-month assessment.

Randomisation and allocation concealment
Eligibility was assessed and written informed consent obtained before enrolment. Group allocation took place after enrolment and completion of baseline assessments. An independent operator prepared the randomisation sequence in advance using a random-number function in Microsoft Excel, with a 1:1 treatment-to-control allocation ratio. This operator had no role in participant recruitment, treatment delivery, or outcome assessment. Allocation was concealed through sealed envelopes numbered consecutively and prepared in advance. Each envelope was opened only after the participant had been enrolled and baseline assessments completed. The principal investigator then became aware of the assigned group and delivered the corresponding intervention. Allocation and treatment proceeded during recruitment, without waiting for recruitment of the entire sample to be completed.

Study coding and confidentiality
After allocation was revealed, each participant was assigned a unique study identifier (SubjectID, Sxxx) and a randomisation code (RANDxxx). The study register documented these codes and the assigned group. The electronic allocation register was password-protected, with access restricted to authorised personnel. The list connecting participants' identities to their study codes was stored separately from the analytical dataset. Statistical analyses used coded records without names or other direct identifiers.

Masking
Participants and the principal investigator were aware of treatment assignment. As the principal investigator performed both treatment and periodontal examinations, the periodontal examiner was also unmasked. Laboratory personnel measuring fasting glucose, HbA1c, and hsCRP were masked to treatment assignment.

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Previous interventions:

The intervention consists of non-surgical periodontal therapy, including full-mouth scaling and root planing performed using manual and/or ultrasonic instruments, combined with standardized oral hygiene instructions. Periodontal re-evaluation and supportive periodontal therapy are conducted at 3 and 6 months to manage residual inflammation and reinforce oral hygiene.

Control Group Methodology
Participants allocated to the control group receive standard oral hygiene instructions and motivation only, without active periodontal treatment during the study period. Oral hygiene education is delivered at baseline and reinforced at the 3- and 6-month follow-up visits. This includes instruction on proper tooth-brushing technique, interdental cleaning, and general advice on plaque control and oral health maintenance.No professional periodontal instrumentation (such as scaling and root planing) is performed in the control group during the active study phase. In accordance with ethical standards, participants in the control group are offered full periodontal treatment after completion of the final 6-month follow-up assessment.

Randomisation Process
Eligible participants are randomly allocated to either the treatment group or the control group

using computer-generated randomisation with a 1:1 allocation ratio. The randomisation sequence is generated prior to study initiation using a random number function in Microsoft Excel. Each participant is assigned a unique study identification code following confirmation of eligibility and written informed consent. Allocation is concealed in a password-protected digital file and is revealed only after baseline assessments are completed. This procedure is used to minimise selection bias and ensure balanced group assignment.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Glycated hemoglobin measured using HbA1c (%) at 0, 3, 6 months

Key secondary outcome(s)
1. Periodontal parameters measured using PD: Probing Depth, CAL: Clinical Attachment Level, BOP: Bleeding on Probing, GI: Gingival Index, PI: Plaque Index at 0,3,6 months

2. Systemic inflammation measured using hsCRP at 0, 3, 6 months

Completion date
28/02/2026

Eligibility

Key inclusion criteria
Current key inclusion criteria as of 10/11/2026:

1. Age 18-70 years
2. T2DM diagnosis
3. HbA1c ≥ 7%
4. At least 10 natural teeth present (≥10), excluding third molars
5. Periodontitis present ≥ 4 teeth, at least one site PD ≥ 5mm
6. BOP ≥ 10%

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Previous key inclusion criteria:

1. Age 18-70 years
2. T2DM diagnosis
3. HbA1c ≥ 7%
4. More than 10 teeth present
5. Periodontitis present ≥ 4 teeth, at least one site PD ≥ 5mm
6. BOP ≥ 10%

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
70 Years

Sex
All

Total final enrolment
89

Key exclusion criteria
1. Professional periodontal treatment within the last 6 months
2. Systemic antibiotics within the last 3 months
3. Systemic diseases that may affect the response or direct periodontal damage
4. Current or previous oral mucosal diseases (e.g. Pemphigus, Lichen planus, Behcet's syndrome, etc.)
5. Pregnancy or breastfeeding
6. Inability to follow up at 0/3/6 months
7. Refusal to consent participation

Date of first enrolment
12/06/2024

Date of final enrolment
31/08/2025

Locations

Countries of recruitment
Albania

Sponsor information

Organisation
University of Medicine Tirana

ROR
https://ror.org/03y2x8717

Funder(s)

Funder type

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	Secondary Analysis	07/07/2026	10/11/2026	Yes	No
Participant information sheet	in Albanian		19/01/2026	No	Yes