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Does weight-loss surgery reduce inflammatory markers in saliva and gum inflammation in adults with obesity and gum disease?

Submission date
24/07/2026

Recruitment status
No longer recruiting

Registration date
27/07/2026

Overall study status
Completed

Last Edited
27/07/2026

Condition category
Oral Health

[_] 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
Obesity and gum disease (periodontitis) are both linked with inflammation in the body. People with obesity often have higher levels of inflammatory substances, which may also affect the health of their gums. Sleeve gastrectomy is a type of weight-loss surgery that reduces the size of the stomach and can help people lose a large amount of weight.

This study aims to find out whether weight-loss surgery can reduce levels of two inflammatory substances in saliva, called interleukin-6 (IL-6) and tumour necrosis factor-alpha (TNF-alpha), and improve signs of gum inflammation. The study will also help researchers improve study procedures and gather information needed to plan a larger future study.

Who can participate?
Adults aged 18 to 65 years can take part if they have obesity and stage I to III periodontitis (gum disease). Participants must have a body mass index (BMI) of at least 40 kg/m², or at least 35 kg /m² with an obesity-related health condition. They must also have at least 12 natural teeth in each jaw.

People cannot take part if they have had recent gum treatment, previous weight-loss surgery, are pregnant or breastfeeding, smoke more than 10 cigarettes per day, have certain medical conditions that affect inflammation, or are taking some medicines that could affect the study results.

What does the study involve?
Participants are randomly assigned to one of two groups. One group undergoes laparoscopic sleeve gastrectomy, while the other receives non-surgical obesity management.

Participants attend study visits at the start of the study and again after 3 months and 6 months. At each visit, researchers:
-Measure height, weight and other body measurements
-Record information about medications and oral hygiene habits

-Carry out a full examination of the gums and teeth
-Collect a saliva sample

The saliva samples are tested to measure levels of IL-6 and TNF-alpha. All participants receive the same oral hygiene advice at the beginning of the study. No routine gum treatment is provided during the study unless it becomes clinically necessary.

What are the possible benefits and risks of participating?
Participants may benefit from regular monitoring of their oral health and obesity-related health measures during the study. People who undergo sleeve gastrectomy may also experience weight loss and related health benefits, although these cannot be guaranteed.

The main risks depend on the treatment group. Participants who undergo sleeve gastrectomy face the usual risks associated with surgery and recovery from an operation. Gum examinations and saliva collection are generally low risk and should cause little discomfort. Participants in the non-surgical management group may not experience the same level of weight loss as those who have surgery.

Where is the study run from?
The study is run from the George Emil Palade University of Medicine, Pharmacy, Science, and Technology of Targu Mures in Romania.

When is the study starting and how long is it expected to run for?
December 2022 to January 2026.

Who is funding the study?
The study is funded by the George Emil Palade University of Medicine, Pharmacy, Sciences and Technology of Targu Mures, Romania.

Who is the main contact?
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Contact information

Type(s)
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Additional identifiers

Research Grant No.
511/2/17.01.2022.

Study information

Scientific Title
Short-term changes in salivary IL-6, TNF-α, and periodontal inflammation following sleeve gastrectomy in patients with obesity: a randomized controlled pilot study

Study objectives
1. To assess feasibility, refine measurement procedures and estimate preliminary effect sizes for a future definitive trial
2. To compare changes in salivary interleukin-6 (IL-6) and tumour necrosis factor-alpha (TNF-alpha) from baseline to 6 months in adults assigned to laparoscopic sleeve gastrectomy versus non-surgical management
3. To compare longitudinal changes in plaque index, bleeding on probing, probing pocket depth and clinical attachment level between the randomized groups
4. To explore associations between salivary IL-6/TNF-alpha and periodontal clinical parameters

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 15/09/2022, Ethics Committee of the George Emil Palade University of Medicine, Pharmacy, Science, and Technology of Targu Mures, Romania. (38 Ghe Marinescu, Targu Mures, 540136, Romania; +40 265215551; prorectorat.stiintific@umfst.ro), ref: 1863/15.09.2022.

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied

Obesity and stage I-III periodontitis

Interventions
After eligibility confirmation, baseline periodontal examination and baseline saliva collection, participants were assigned to one of two parallel groups by simple computer-generated randomization without blocking or stratification. The allocation sequence was generated before recruitment by an investigator not involved in periodontal examination or laboratory analysis. Assignments were placed in sequentially numbered, opaque, sealed envelopes and opened only after baseline measurements were completed.

Sleeve gastrectomy group: Participants assigned to this group underwent laparoscopic sleeve gastrectomy. Baseline was the preoperative visit. Follow-up assessments were scheduled at 3 and 6 months.

Non-surgical management group: Participants assigned to this group received non-surgical obesity management, with baseline at enrolment and follow-up at 3 and 6 months.
All participants received standardized oral-hygiene instructions at baseline and were advised to maintain their usual oral-care habits. No periodontal treatment was provided during follow-up unless clinically necessary. At baseline, 3 months and 6 months, the study recorded anthropometry, background medication and self-reported oral-hygiene variables, performed a full-mouth periodontal examination, and collected unstimulated whole saliva for IL-6 and TNF-alpha measurement.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Salivary interleukin-6 concentration measured using Concentration in pg/mL measured in unstimulated whole saliva using a commercially available enzyme-linked immunosorbent assay (ELISA). Samples were assayed in duplicate and the mean result was used at baseline, 3 months and 6 months; the principal comparison was change from baseline to 6 months

2. Salivary tumour necrosis factor-alpha concentration measured using Concentration in pg/mL measured in unstimulated whole saliva using a commercially available enzyme-linked immunosorbent assay (ELISA). Samples were assayed in duplicate and the mean result was used at baseline, 3 months and 6 months; the principal comparison was change from baseline to 6 months

Key secondary outcome(s)

Completion date
20/01/2026

Eligibility

Key inclusion criteria
1. Age 18-65 years
2. Body mass index (BMI) >=35 kg/m² with obesity-related comorbidities, or BMI >=40 kg/m²
3. Stage I-III periodontitis according to the 2018 periodontitis stage/grade classification
4. At least 12 natural teeth per arch to permit reliable periodontal examination

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
65 Years

Sex
All

Total final enrolment
31

Key exclusion criteria
1. Smoking more than 10 cigarettes per day
2. Periodontal treatment within the previous 6 months
3. Pregnancy or lactation
4. Previous bariatric surgery
5. Systemic diseases known to markedly affect periodontal inflammation, including active autoimmune disorders or malignant disease
6. Recent antibiotic use
7. Recent systemic corticosteroid use
8. Regular non-steroidal anti-inflammatory drug use within 90 days
9. Current anti-obesity glucagon-like peptide-1 (GLP-1) therapy

Date of first enrolment
01/12/2022

Date of final enrolment
06/04/2025

Locations

Countries of recruitment
Romania

Sponsor information

Organisation
George Emil Palade University of Medicine, Pharmacy, Science, and Technology of Targu Mures

Funder(s)

Funder type

Funder Name
Universitatea de Medicină, Farmacie, Științe și Tehnologie "George Emil Palade" din Târgu Mureș

Alternative Name(s)
“George Emil Palade” University of Medicine, Pharmacy, Sciences and Technology from Târgu Mureș, UMFST G.E. Palade Tg.Mureș, UMF, Tîrgu-Mureș

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Romania

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available