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Effect of natural compounds on bacterial plaque

Submission date	Recruitment status	[_] Prospectively registered
25/03/2025	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
26/03/2025	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
25/03/2025	Oral Health	[X] Record updated in last year

Plain English summary of protocol

Background and study aims

Dental plaque is a sticky layer of bacteria that builds up on teeth and can lead to tooth decay (cavities) and gum disease if it isn't removed regularly. While chemical mouthwashes like chlorhexidine are effective at reducing plaque, they can cause side effects such as staining of the teeth or a change in taste. Because of this, there is growing interest in safer, natural alternatives.

Two natural substances - propolis (a resin-like product made by bees) and green tea extract - have been shown to have antibacterial effects and have traditionally been used to help with oral health. Some early research suggests they might help reduce dental plaque, but more studies are needed to confirm how well they work compared to standard treatments.

This study was carried out to find out whether mouthrinses made with propolis or green tea could reduce dental plaque comparable to chlorhexidine. The researchers also wanted to see if these natural rinses were safe to use and whether people would use them regularly.

Who can participate?

Patients aged 18 years and over who are suffering from gingivitis

What does the study involve?

Participants will be randomly allocated to receive professional mechanical plaque removal accompanied by either propolis mouthwash, green tea mouthwash, 0.2% chlorhexidine mouthwash (positive control), or placebo rinse. Follow-up will be at 7, 14 and 28 days.

What are the possible benefits and risks of participating?

Participants may benefit from improved gum health and reduced inflammation. No risk is incurred by the use of the antimicrobial product.

Where is the study run from?

Department of Dental Medicine of the Vasile Goldiș Western University of Arad (Romania)

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

October 2022 to September 2023

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Lile Ioana, lile.ioana@uvvg.ro

Contact information

Type(s)
Public, Scientific, Principal Investigator

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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
Symbiosis in oral health: the role of natural compounds in dental plaque management

Acronym
OH-GI-NAT-COMP

Study objectives
The null hypothesis (H0) was that no statistically significant differences are observed with respect to the clinical parameters pocket probing depth (PPD), bleeding on probing (BoP), plaque index (PI) and full mouth bleeding score (FMBS) between the treatment modalities.

Ethics approval required

Ethics approval required

Ethics approval(s)
Approved 10/01/2025, Research Ethics Committee of the Vasile Goldis University of Arad (bd. Revolutiei nr. 94, Arad, 310130, Romania; +40 (0)257 280 260; eticacercetarii@uvvg.ro), ref: 01/10/01/2025

Study design
Prospective single-blind randomized placebo-controlled clinical trial with a parallel-group design and a 4-week duration

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Dental clinic

Study type(s)
Treatment

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

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

Interventions
Prior to treatment, full-mouth supragingival scaling was performed in all subjects. Each patient was assigned to one of the four treatment groups according to computer-generated randomization. Participants will be randomly allocated to receive professional mechanical plaque removal (PMPR) accompanied by either propolis mouthwash, green tea mouthwash, 0.2% chlorhexidine mouthwash (positive control), or placebo rinse. Follow-up will be at 7, 14 and 28 days.

Intervention Type
Procedure/Surgery

Primary outcome measure
Plaque measured using plaque index (PI) at baseline and 4 weeks

Secondary outcome measures
1. Gingival inflammation measured using the Gingival Index (GI) at baseline and 4 weeks
2. Patient-reported satisfaction measured using a questionnaire at baseline and 4 weeks
3. Pocket probing depth (PPD) measured using a manual periodontal probe (UNC-15) at six sites per tooth at baseline and 4 weeks
4. Bleeding on probing (BoP) measured using a manual periodontal probe (UNC-15) at six sites per tooth at baseline and 4 weeks

5. Bleeding measured using the Full Mouth Bleeding Score (FMBS) at baseline and 4 weeks
6. Plaque measured using the Full Mouth Plaque Score (FMPS) at baseline and 4 weeks

Overall study start date
01/10/2024

Completion date
03/09/2025

Eligibility

Key inclusion criteria
1. Age 18–50 years, systemically healthy
2. Minimum of 20 natural teeth present
3. Moderate plaque accumulation (baseline Plaque Index score between 1.5-3.0)
4. No professional dental cleaning within the past 3 months

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
50 Years

Sex
Both

Target number of participants
60 patients divided into 4 groups (15 patients per group)

Key exclusion criteria
1. Any systemic condition requiring antibiotic prophylaxis
2. Use of antibiotics or antiseptic mouthrinses in the last 4 weeks
3. Ongoing dental treatment or recent periodontal therapy
4. Known allergy to any product ingredients (propolis, tea, or chlorhexidine)
5. Pregnant or lactating women
6. Failure to sign written informed consent

Date of first enrolment
10/01/2025

Date of final enrolment
10/04/2025

Locations

Countries of recruitment
Romania

Study participating centre
Dental Medicine of the Vasile Goldiş Western University of Arad
Str. Liviu Rebreanu, Nr. 86, Campusul Universitar
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Sponsor information

Organisation
Vasile Goldis Western University of Arad

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Sponsor type
University/education

Website
https://www.uvvg.ro/

ROR
https://ror.org/01e0stw12

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
It is planned to publish the results in a dental medicine journal

Intention to publish date
09/09/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analyzed during the study will be stored in a non-publically available repository: the archives of the Department of Dental Medicine of the Vasile Goldiș Western University of Arad. The data will become available 5 years after the end of the study, indefinitely. Data anonymisation: numbers were attributed to patients' names.

IPD sharing plan summary
Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			25/03/2025	No	Yes