

Nonsurgical approach for the treatment of periodontal diseases

Submission date 28/12/2025	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 30/12/2025	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 30/12/2025	Condition category Oral Health	☐ Individual participant data

Plain English summary of protocol

Plain English summary of protocol not provided at time of registration.

Contact information

Type(s)

Public

Contact name

Prof Gagik Hakobyan

Contact details

Kievyan 10/65
Yerevan
Armenia
0025
+37491403038
prom_hg@yahoo.com

Type(s)

Scientific

Contact name

Prof Lazar Yessayan

Contact details

2 Koryuni
Yerevan
Armenia
0025
+37494422222
lasyes@yandex.ru

Type(s)

Principal investigator

Contact name

Mr Viktoria Margaryan

Contact details

2 Koryuni

Yerevan

Armenia

0028

+374033352050

viki199813@mail.ru

Additional identifiers**Study information****Scientific Title**

Adjunctive therapy – a promising method in the treatment of periodontal disease

Study objectives

The study aims to compare the clinical efficacy of the application of "Armenicum" paste as an adjunct to SRP for the nonsurgical treatment of patients with periodontitis.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 22/01/2025, Yervan State Medical University (Koryun 2, Yerevan, 0025, Armenia; +374 10 58 25 32; info@ysmu.am), ref: 24

Primary study design

Interventional

Allocation

Randomized controlled trial

Masking

Blinded (masking used)

Control

Active

Assignment

Parallel

Purpose

Treatment

Study type(s)

Health condition(s) or problem(s) studied

Periodontitis according to the World Classifications of 2017.

Interventions

The patients were randomly assigned into two groups using computer-generated randomisation: Group A (SRP + Armenicum" paste) and Group B (SRP). Group A underwent a periodontal treatment which included: supragingival and subgingival scaling, and additional use of local "Armenicum" paste.

Under local anesthesia, supragingival and subgingival scaling(with an ultrasonic scaler and root planning using Gracey curettes). Immediately after (SRP), the teeth were isolated with cotton rolls and the paste "Armenicum" paste was gently applied once with a syringe inside the pocket and the top of the gum area. Within 3 h of applying the paste, patients were advised not to eat, drink or brush their teeth. "Armenicum" was applied for ten days under a bandage on the gums for 10 procedures lasting thirty minutes. The Group B group only received supragingival and subgingival scaling.

Group B protocol periodontal treatment includes: supragingival and subgingival scaling and root debridement (with an ultrasonic device and root planning using Gracey curettes). The therapy was also performed under local anesthesia.

Patients were instructed to start rinsing 24 h after therapy with a 0.12% chlorhexidine solution for 2 weeks, twice daily.

After comprehensive treatment of periodontitis, all patients had assessments and were indexed: (1) dental plaque index (PI); (2) bleeding on probing (BOP); (3) probing pocket depth (PPD).

Intervention Type

Supplement

Primary outcome(s)

1. The amount and thickness of bacterial plaque on tooth surfaces measured using the Dental plaque index (PI) at baseline, 3 and 6 months
2. Bleeding on probing (BOP) measured using the BOP index following an examination after 30 s of each probed site at baseline, 3 and 6 months
3. Probing pocket depth (PPD) measured using a full millimeter with a manual periodontal probe between the gingival margin and the base of the periodontal pocket, 6 sites per tooth (mesio-buccal, midbuccal, disto-buccal, mesio-palatal, mid-palatal, and disto-palatal) at baseline, 3 and 6 months
4. Gum inflammation measured using the gingival bleeding index at baseline, 3 and 6 months

Key secondary outcome(s)

Completion date

28/12/2025

Eligibility

Key inclusion criteria

1. Stage I or stage II of chronic periodontitis
2. A minimum of 24 remaining teeth
3. Non-smokers
4. Systemically healthy
5. Not received any previous periodontal treatment (within the previous year)
6. No antibiotic therapy or chemotherapeutic mouth-rinse or oral irrigation (within the last 6 months)
7. Can perform oral hygiene self-care and are committed to post-treatment follow-up visits

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

37 Years

Upper age limit

68 Years

Sex

All

Total final enrolment

157

Key exclusion criteria

1. Systemic diseases
2. Smokers
3. Pregnant and lactating females
4. Previous periodontal treatment (during the previous year) or antibiotic intake (during the past 3 months)

Date of first enrolment

28/01/2025

Date of final enrolment

28/07/2025

Locations**Countries of recruitment**

Armenia

Sponsor information

Organisation
Astra Science LLC

Funder(s)

Funder type

Funder Name
Yerevan State University

Alternative Name(s)
Ереванский государственный университет, , YSU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Armenia

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		23/01/2025	30/12/2025	Yes	No