ISRCTN29615137 https://doi.org/10.1186/ISRCTN29615137

Nonsurgical approach for the treatment of periodontal diseases

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

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