

Participant Information Sheet

Study title

Topical polyherbal phytopreparation as an adjunct to scaling and root planing in patients with periodontitis: randomized controlled clinical study

Invitation to take part

Institution: Faculty of Medicine, University of Niš, Serbia, Dental Clinic, Department of Oral medicine and periodontology

What is the purpose of the study?

The purpose of this study is to evaluate whether a topical polyherbal phytopreparation (Tinctura paradentonica®) used in addition to standard non-surgical periodontal therapy (scaling and root planing, SRP) can improve gum inflammation and periodontal clinical outcomes.

Why have I been invited?

You have been invited because you have been diagnosed with periodontitis and meet the eligibility criteria for this study.

Do I have to take part?

No. Taking part is entirely voluntary. If you decide not to take part, your routine treatment and care will not be affected in any way. If you decide to take part, you are still free to withdraw at any time without giving a reason.

What will happen if I take part?

If you agree to participate, you will attend a baseline visit, receive standard periodontal therapy, and then attend a follow-up visit after one month.

Study groups (randomization)

Participants will be randomly allocated to one of two groups:

- Control group: standard scaling and root planing (SRP) only
- Experimental group: SRP plus topical application of the polyherbal phytopreparation

Randomization means that the group assignment is decided by chance.

Procedures and visits

1. Baseline assessment: examination of gum condition and periodontal measurements.
2. Treatment: SRP performed over consecutive visits as standard of care. If you are in the experimental group, the phytopreparation will be applied locally into periodontal pockets.
3. Follow-up assessment (1 month): repeat clinical measurements (clinical indices and cytomorphometric analyses).

What are the possible benefits of taking part?

You may experience improvement in gum inflammation and periodontal health. However, we cannot guarantee that you will benefit directly. The information gained from this study may benefit future patients.

What are the possible risks or disadvantages?

Scaling and root planing can cause temporary discomfort, tooth sensitivity, or slight gum bleeding. The phytopreparation is applied locally; mild irritation or sensitivity is possible, although side effects are not expected.

Will my taking part in this study be kept confidential?

Yes. Your data will be coded so that you are not personally identified in study files. Only authorized study personnel will have access to information that could identify you. Results may be published, but you will not be identifiable.

What will happen to the results of the research study?

Results may be presented at scientific meetings and published in journals. No participant will be identifiable in any report or publication.

Who is organizing and funding the research?

Institution: Faculty of Medicine, University of Niš, Serbia was organized, but the study was not sponsored. It was conducted as part of a project and as an academic clinical research.

Ethical approval

The study has received ethical approval from the Faculty of Medicine, University of Niš Ethics Committee (Approval No.: 12-6422-2/7).

Contact for further information

Principal Investigator: Milica Petrović

Institution: Faculty of Medicine, University of Niš, Serbia

Email: milica.petrovic@medfak.ni.ac.rs

Telephone: +38164 237 3966