

# Clinical Study Protocol

## Protocol title

Efficacy of a topical polyherbal phytopreparation as an adjunct to scaling and root planing in patients with periodontitis: a randomized controlled clinical study

## Trial registration

Retrospective registration in a WHO ICTRP Level 1 registry / ICMJE-accredited platform (e.g., ISRCTN).

## Background and rationale

Periodontitis is a chronic inflammatory disease driven by dysbiotic biofilm and host response. Herbal products may provide adjunctive anti-inflammatory and antimicrobial effects. This study evaluates a polyherbal phytopreparation as an adjunct to standard non-surgical periodontal therapy.

## Objectives

*Primary objective:* to assess change in gingival inflammation following adjunctive topical polyherbal phytotherapy compared with SRP alone.

*Secondary objective:* to assess change in periodontal pocket depth and related outcomes.

## Study design

- Randomized controlled clinical study, two parallel groups
- Allocation concealment using sequentially numbered, opaque sealed envelopes
- Blinding: participants and recruiting investigators blinded; assessor blinded

## Study setting

Institution: Faculty of Medicine, University of Niš, Serbia

## Eligibility criteria

### Inclusion criteria

- Adults diagnosed with periodontitis (Stage II, Grade A) according to the 2018 classification
- Systemically healthy

- At least 24 natural teeth
- Radiographic evidence of bone loss

### **Exclusion criteria**

- Smoking or significant alcohol consumption
- Systemic diseases affecting periodontal tissues
- Use of hormonal therapy/contraceptives, corticosteroids, immunosuppressants
- History of radiotherapy or chemotherapy

### **Interventions**

#### **Control group**

Standard non-surgical periodontal therapy (scaling and root planing – SRP), performed according to clinical protocol.

#### **Experimental group**

SRP plus adjunctive topical polyherbal phytopreparation applied subgingivally (0.1 mL per pocket) under isolation conditions for two minutes per quadrant.

#### **Concomitant care**

All participants receive the same standard periodontal therapy and oral hygiene instructions. No additional antimicrobial agents are provided as part of the study intervention.

#### **Outcomes**

*Primary endpoint:* change in Gingival Index (GI) from baseline to 1 month.

*Key secondary endpoint:* change in Periodontal Pocket Depth (PPD) from baseline to 1 month.

*Exploratory outcomes:* cytomorphometric parameters of gingival epithelial cells.

#### **Sample size**

Planned sample size: 80 participants (40 per group).

#### **Randomization and blinding**

Random assignment with 1:1 ratio. Allocation concealment ensured by sealed envelopes. Blinding maintained for participants and recruiting investigators; clinical assessments performed by a blinded assessor.

**Data collection and management**

Clinical indices and measurements are recorded in case report forms. Data are coded and stored securely with restricted access.

**Safety monitoring**

Adverse events will be recorded and assessed throughout participation. Participants may contact investigators at any time in case of concerns or side effects.

**Ethics and dissemination**

Ethics approval obtained from the Faculty of Medicine, University of Niš Ethics Committee (Approval No.: 12-6422-2/7). Results will be disseminated through publication and scientific presentations.