

A cost-effective method utilizing both povidone-iodine irrigations and sodium hypochlorite rinsing solution as supplementary measures in treating severe gum disease, aimed at reducing bacterial infections in patients

Submission date 13/03/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 13/03/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 01/04/2026	Condition category Oral Health	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Severe cases of gum disease, known as periodontitis, often do not respond well to typical treatments due to the presence of bacteria and viruses. Simply using mechanical methods to clean the gums may not be enough to remove a significant amount of these harmful microorganisms, especially in deep gum pockets.

The goal of this study is to compare the effectiveness of a low-cost treatment method using povidone-iodine and sodium hypochlorite solutions alongside regular gum cleaning, with the more commonly used Chlorhexidine solution, in patients with advanced stage IV periodontitis. The study aims to assess both the clinical outcomes (how the patients' gums look and feel) and the microbiological outcomes (the levels of harmful bacteria) of these different treatment approaches.

Who can participate?

Patients who are generally healthy and have been diagnosed clinically with severe stages of gum disease, specifically stage III and IV, with grades B and C severity, as defined by the Classification of Periodontal and Peri-implant Diseases and Conditions in 2018.

What does the study involve?

Forty-five patients were randomly assigned to one of two groups: the control group, where subgingival cleaning was done with the help of chlorhexidine, and the test group, where antiviral medication was used alongside subgingival cleaning with povidone-iodine, sodium hypochlorite rinsing, and antibiotics. Clinical evaluations and analysis of the bacteria present were conducted at the beginning of the study and again after three months.

What are the possible benefits and risks of participating?

The possible benefits are substantial improvements in clinical and microbiological parameters, when compared with the current antimicrobial recommendations.
There are no risks involved for the participants.

Where is the study run from?

Victor Babeş University of Medicine and Pharmacy Timișoara (Romania)

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

January 2019 to November 2023

Who is funding the study?

Investigator initiated and funded

Who is the main contact?

Prof. Marius Boariu, boarium@yahoo.com

Contact information

Type(s)

Public, Scientific, Principal investigator

Contact name

Prof Marius Boariu

ORCID ID

<https://orcid.org/0000-0001-6184-3704>

Contact details

Bv.Revolutiei de la 1989, 9

Timișoara

Romania

300070

+40 722701871

boariu.marius@umft.ro

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Protocol serial number

01/2020/PERIO

Study information

Scientific Title

A low-cost protocol using the adjunctive action of povidone-iodine irrigations and sodium hypochlorite rinsing solution to Step 2 of periodontal therapy for patients with stage III-IV periodontitis. A single-blind randomized controlled trial

Acronym

LOW-COST-STEP-II

Study objectives

The hypothesis of the study is that a complex treatment protocol including low-cost potent antimicrobials, antivirals and antibiotics, as adjunctive to subgingival instrumentation, will result in better clinical and microbiological outcomes than the traditional subgingival instrumentation, in patients with severe periodontitis.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 12/10/2020, The Research Ethics Committee of the 'Victor Babeş' University of Medicine and Pharmacy Timisoara (Pta Eftimie Murgu nr. 2, Timișoara, 300041, Romania; +40 256204400; esanda2000@yahoo.com), ref: 56/2020

Study design

Single-blind randomized controlled trial interventional single-center

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Periodontitis stages III-IV

Interventions

45 patients were randomly divided into two groups control (subgingival instrumentation chlorhexidine-assisted) and test (antiviral medication, subgingival instrumentation with povidone-iodine, sodium hypochlorite rinsing solution and antibiotics). Clinical measurements and microbiological analysis were performed at baseline and after three months.

Intervention Type

Mixed

Primary outcome(s)

Pocket Depth (PD) reduction. PDs were measured at six sites/tooth using a PCP-UNC calibrated probe (Hu-Friedy, Chicago, IL, USA), at baseline and after 3 months.

Key secondary outcome(s)

1. Full-mouth plaque scores (FMPS) were recorded using six sites per tooth. The presence of plaque was determined using disclosure solution (Dentorama Blue Disclosing Pellets Pro-155, Svenska Dentorama AB, Solna/Stockholm, Sweden), in a dichotomic way, with regard to the percentage of sites with plaque.
2. Bleeding on probing (BOP) was assessed dichotomously in 6 sites per tooth, using a periodontal probe (Force-Control Periodontal Probe WHO DB765R, Aesculap, Tuttlingen, Germany).

3. Recession (REC) were recorded to the nearest millimeter at six sites per tooth.
4. The clinical attachment level (CAL) was calculated using the PD and REC values. Measurements were rounded up to the next whole millimeter value. At the proximal surfaces, the evaluation was done in the proximity of the dental contact point, with moderate pressure. For all clinical measurements the probing force was 0.2N (20 g) using the same standardized periodontal probe.
5. Mobility was recorded in degrees, according to the Miller classification system (1985) (40). The periodontal parameters were recorded in the periodontal chart (<http://www.periodontalchart-online.com/uk/>), saved in .pdf format, printed and included into each patient's observation file.

Other secondary outcomes:

6. Microbiological data: In the same appointment, bacterial samples were taken as described below: to detect the 5 major keystone bacteria, *Aggregatibacter actinomycetemcomitans* (Aa), *Porphyromonas gingivalis* (Pg), *Prevotella intermedia* (Pi), *Tannerella forsythia* (Tf), and *Treponema denticola* (Td), a molecular genetic analysis was performed, using the commercial kit micro-IDent plus (Hain Lifescience GmbH). During the initial evaluation, samples of subgingival plaque were collected from the deepest periodontal pockets in each quadrant and used to identify the existing bacterial strains prior to treatment. This protocol was repeated at the three-month re-evaluation to assess post treatment bacterial suppression. Samples were collected by using four sterile paper points #25 (ProTaper Next® Paper Points X2; Dentsply Sirona) that were inserted into the gingival sulcus after having removed any supragingival plaque with sterile cotton gauzes, isolated the site with cotton rolls, and taken measures to avoid contamination with saliva. After the targeted tooth surface was dried with a gentle air spray, the paper points were left in situ for 30 sec until they were completely soaked. Bacterial analyses were repeated at three months.

Patient-centered data:

7. Patient-centered data regarding the perception of the recommended concentration of hypochlorite were collected using a VAS scale. Perception of the taste during use, tolerance, oral dryness sensation, and esthetic impact of staining after three months of use were evaluated by the patient on a scale from 1 to 10. Other subjective perceptions regarding the taste modifications, oral mucosa irritations, long-term negative effects, the intensity of the sensation of cleanliness, ease of solution preparation, and economic impact were collected and evaluated on a 1 to 5 scale of approval.

Completion date

30/11/2023

Eligibility

Key inclusion criteria

Systematically healthy patients with the clinical diagnosis of periodontitis stage III and IV, grades B and C, according to the Classification of Periodontal and Peri-implant Diseases and Conditions 2018.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

33 years

Upper age limit

71 years

Sex

All

Total final enrolment

45

Key exclusion criteria

Current exclusion criteria as of 12/04/2024:

1. Patients who underwent antibiotic, anticoagulant or immunosuppressive therapy during the preceding 6 months
2. Patients who used oral antiseptics or received any periodontal therapy
3. Pregnant or lactating women
4. Patients in need of antibiotic prophylaxis during the preceding six months
5. Hypersensitivity against PVP-iodine and NaOCl
6. Thyroid dysfunction
7. Patients with allergies to the recommended medications
8. Systemic disorders
9. Smokers (≥ 10 cigarettes per day)

Previous exclusion criteria:

1. Patients who underwent antibiotic, anticoagulant or immunosuppressive therapy during the preceding 6 months
2. Patients who used oral antiseptics or received any periodontal therapy
3. Pregnant or lactating women
4. Patients in need of antibiotic prophylaxis during the preceding six months
5. Hypersensitivity against PVP-iodine and NaOCl
6. Thyroid dysfunction
7. Patients with allergies to the recommended medications
8. Systemic disorders
9. Non-smokers and smokers (≤ 10 and ≥ 10 cigarettes per day) were included, and a separate analysis was carried out for each category.

Date of first enrolment

01/09/2021

Date of final enrolment

01/03/2023

Locations

Countries of recruitment

Romania

Study participating centre

Department of Peridontology, Faculty of Dentistry, Victor Babes University of Medicine and Pharmacy Timisoara Romania

Bv.Revolutiei de la 1989, 9

Timișoara

Romania

300070

Sponsor information

Organisation

Victor Babeș University of Medicine and Pharmacy Timișoara

ROR

<https://ror.org/00afdp487>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during the current study will be available upon request from Prof. Marius Boariu, boarium@yahoo.com

IPD sharing plan summary

Available on request, Stored in non-publicly available repository

Study outputs

Output type

Details

Date created

Date added

Peer reviewed?

Patient-facing?

Results article		14/05/2024	01/04/2026	Yes	No
Other unpublished results	version 1	20/03/2024	04/06/2024	No	No