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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

Registration date
13/03/2024

Overall study status
Completed

Last Edited
04/06/2024

Condition category
Oral Health

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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 Babeș 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

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
University/medical school/dental school

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

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 measure
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.

Secondary outcome measures
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 gingi-valis (Pg), Prevotella intermedia (Pi), Tanererella 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.

Overall study start date

01/01/2019

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

Age group
Adult

Lower age limit
33 Years

Upper age limit
71 Years

Sex
Both

Target number of participants
45

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)

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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
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Funder(s)

Funder type
Other

Funder Name
Investigator intiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
29/02/2024

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
Stored in non-publicly available repository, Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other unpublished results	version 1	20/03/2024	04/06/2024	No	No