

Sodium hypochlorite formulation as an adjunct to nonsurgical periodontal treatment

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Registration date 22/07/2025	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 22/07/2025	Condition category Oral Health	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Periodontitis is a chronic inflammatory disease leading to the bone and soft tissue loss and, consequently, to tooth loss. Scaling and root planing (SRP) is the basic therapeutic procedure in the treatment of periodontitis. Due to the limitations of SRP and the multifactorial etiology of periodontal disease, new methods are being sought to support mechanotherapy. One of them is the local use of antiseptics such as low-concentration sodium hypochlorite formulation. Therefore, the aim of the study was to clinically evaluate periodontal parameters and take the samples of the gingival crevicular fluid after SRP with intrapocket application of a new preparation with low-concentrated sodium hypochlorite and without the use of the formulation.

Who can participate?

Adults (18+ years) with periodontitis.

What does the study involve?

The study involves scaling and root planing with and without sodium hypochlorite formulation. Before SRP, the patients in the study group will have a gel with low-concentration sodium hypochlorite introduced into pockets with depth over 5 mm. The patients in the control group will have SRP alone. Clinical examination of periodontium will be done and gingival crevicular fluid will be taken to further analysis.

What are the possible benefits and risks of participating?

Possible benefit of participating is decrease in periodontal pocket depth.

Possible risks are the same as routine dental visit. The low concentration sodium hypochlorite formulation will be used according manufacturer instructions.

Where is the study run from?

Study is run at Medical University of Bialystok (Poland)

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

January 2020 to May 2022

Who is funding the study?

The study is funded by Medical University of Bialystok (Poland)

Who is the main contact?

The main contact is Dr hab. n. med Ewa Dolińska (ewa.dolinska@umb.edu.pl)

Contact information

Type(s)

Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Protocol serial number

Medical University of Bialystok : SUB/1/DN/20/003/1164

Study information

Scientific Title

Sodium hypochlorite formulation as an adjunct to nonsurgical periodontal treatment-a prospective randomized clinical trial

Study objectives

There are no clinical differences between non-surgical periodontal treatment and non-surgical periodontal treatment preceded by application of a sodium hypochlorite-based formulation.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 23/09/2020, Bioethics Committee of Medical University of Bialystok (ul. Kilińskiego 1, Białystok, 15-089, Poland; 85 748 54 07; komisjabioetyczna@umb.edu.pl), ref: APK.002.269.2020

Study design

Interventional single-blinded randomized controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Nonsurgical periodontal treatment

Interventions

Patients are randomly allocated to study or control group. Randomization is based on a computer-generated list.

Patients randomized to the study group are treated non-surgically (SRP, scaling and root planing) according to the following procedure: after a periodontal examination, a preparation with NaOCl/AA (Perisolv®) is applied into the pockets with PD \geq 5 mm. The formulation is prepared immediately before application by mixing the contents of two syringes. A gel is introduced into the pockets with PD \geq 5 mm with a sterile applicator. The gel is left in place for 30 seconds. This is followed by a total subgingival scaling and root planing using an EMS Piezon ultrasonic scaler (EMS) with a PS tip (Perio Slim).

In the control group, the SRP procedure is performed with the same instruments without Perisolv® application.

Clinical examination is planned at baseline, 3 months and 6 months.

Gingival crevicular fluid collection is planned 1 week, 2 weeks, 3 months and 6 months.

Intervention Type

Mixed

Primary outcome(s)

1. Probing depth (PD) is measured using a manual PCP UNC 15 periodontal probe (Hu-Friedy, Chicago, IL, USA), calibrated in 1 millimeter increments at baseline, 3 months and 6 months.
2. Number of deep periodontal pockets i.e. pockets with PD \geq 5 mm is counted at baseline, 3 months and 6 months. Pockets that were PD \geq 5 mm at baseline and become PD $<$ 5 mm are counted as 'closed' pockets.

Key secondary outcome(s)

1. Clinical attachment level gain (CAL) and gingival recession (GR) are measured using a manual PCP UNC 15 periodontal probe (Hu-Friedy, Chicago, IL, USA), calibrated in 1 millimeter increments at baseline, 3 months and 6 months.
2. Full mouth plaque score (FMPS) is measured using manual PCP UNC 15 periodontal probe (Hu-Friedy, Chicago, IL, USA), calibrated in 1 millimeter increments at baseline, 3 months and 6 months. Presence of plaque is checked on 6 surfaces of each tooth.
3. Full mouth bleeding on probing (FMBOP) is measured using a manual PCP UNC 15 periodontal probe (Hu-Friedy, Chicago, IL, USA), calibrated in 1 millimeter increments at baseline, 3 months and 6 months. Bleeding on probing is assessed in 6 points on every tooth.
4. Additionally at baseline, 1 week, 2 weeks, 3 months and 6 months gingival crevicular fluid is taken for laboratory analyses.

Completion date

05/05/2022

Eligibility

Key inclusion criteria

1. Diagnosed with periodontitis stage II or III, grade B or C
2. Presence of at least 16 teeth (with at least 4 in each quadrant)
3. Presence of at least 4 deep periodontal pockets (PD \geq 5 mm)
4. No professional hygiene procedures in the last 6 months
5. No systemic antibiotic therapy in the last 3 months
6. Age over 18 years
7. Being a non-smoker

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

40

Key exclusion criteria

1. General contraindications to any periodontal therapy
2. Immunosuppression or immunological incompetence
3. Uncontrolled diabetes
4. Pregnancy and breastfeeding
5. Alcohol and/or drug dependence
6. Patient requiring antibiotic cover prior to periodontal therapy
7. Patient with no opportunity to participate in the programme for 6 months

Date of first enrolment

01/10/2020

Date of final enrolment

30/09/2021

Locations

Countries of recruitment

Poland

Study participating centre

Department of Periodontal and Oral Mucosa Diseases, Medical University of Białystok
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Sponsor information

Organisation

Medical University of Białystok

ROR

<https://ror.org/00y4ya841>

Funder(s)

Funder type

University/education

Funder Name

Medical University of Białystok

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during this study are available upon reasonable request from Ewa Dolińska (ewa.dolinska@umb.edu.pl).

IPD sharing plan summary

Available on request