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Sodium hypochlorite formulation as an adjunct to nonsurgical periodontal treatment

Submission date
10/06/2025

Recruitment status
No longer recruiting

Registration date
22/07/2025

Overall study status
Completed

Last Edited
22/07/2025

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] 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 hypoclorite 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

Contact name
Dr Ewa Dolińska

ORCID ID
https://orcid.org/0000-0003-3122-4990

Contact details
ul.Waszyngtona 13
Białystok
Poland
15-269
+48 857485905
ewa.dolinska@umb.edu.pl

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Dental clinic

Study type(s)
Treatment

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

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 ≥ 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≥5mm 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, 2weeks, 3 months and 6 months.

Intervention Type
Mixed

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

Secondary outcome measures
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 milimeter 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 milimeter 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 milimeter increments at baseline, 3 months and 6 months. Bleeding on probing is assesed 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 labolatory analyses.

Overall study start date
10/01/2020

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 ≥ 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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

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 Bialystok
ul Waszyngtona 13
Bialystok
Poland
15-269

Sponsor information

Organisation
Medical University of Białystok

Sponsor details
ul Kilińskiego 1
Bialystok
Poland
15-089
+48 85 7485400
kancelaria@umb.edu.pl

Sponsor type
University/education

Website
https://www.umb.edu.pl

ROR
https://ror.org/00y4ya841

Funder(s)

Funder type
University/education

Funder Name
Medical University of Białystok

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviwed journal.

Intention to publish date
01/09/2025

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