ISRCTN17852953 https://doi.org/10.1186/ISRCTN17852953

Clinical, microbiological and enzymatic evaluation after "Clean&Seal® protocol in subgingival instrumentation in severe periodontitis (C&S-STEP2)

Submission date 23/11/2024	**Recruitment status** Recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [X] Record updated in last year
Registration date 29/11/2024	**Overall study status** Ongoing	
Last Edited 29/11/2024	**Condition category** Oral Health	

Plain English summary of protocol

Background and study aims
This study aims to evaluate the effectiveness of adding cross-linked hyaluronic acid (xHyA, Hyadent BG®) to the “Clean&Seal®” protocol for treating advanced gum disease (stage III and IV periodontitis). The study will compare this new approach to using Perisolv® alone and a placebo.

Who can participate?
Adults with at least four deep gum pockets (≥5 mm) and significant bone loss (≥3 mm) who have at least 10 remaining teeth can participate. Participants must not have had recent periodontal or antibiotic treatment, certain severe dental conditions, or systemic diseases like uncontrolled diabetes. Pregnant or breastfeeding women, immunocompromised individuals, and those allergic to NaOCl are also excluded.

What does the study involve?
Participants will be randomly assigned to one of three groups: one receiving xHyA and Perisolv®, one receiving Perisolv® alone, and one receiving a placebo gel. All participants will undergo gum cleaning procedures under local anesthesia. Clinical, microbiological, and enzymatic parameters will be measured at the start and three months after treatment.

What are the possible benefits and risks of participating?
Participants may benefit from improved gum health and reduced inflammation. However, there are risks associated with any dental procedure, including discomfort and potential allergic reactions.

Where is the study run from?
The study is conducted at the University Clinic of Periodontology, Victor Babeș University of Medicine and Pharmacy, Timișoara (Romania)

When is the study starting and how long is it expected to run for?
November 2024 to July 2027

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Elena Catana, elena.catana@umft.ro

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
CE-1-2024

Study information

Scientific Title
Clinical, microbiological and enzymatic evaluation of hyaluronic acid used in the "Clean&Seal®" protocol in step 2 of the therapy of the severe and the advanced periodontitis

Acronym
C&S-STEP2

Study objectives
Clean&seal protocol in subgingival instrumentation in step 2 of periodontal treatment results in better clinical, microbiological and enzymatic outcomes than Perisolv alone and placebo.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 04/11/2024, The Committee on Research Ethics of the Victor Babes University of Medicine and Pharmacy Timisoara (Pta Eftimie Murgu 2A, Timisoara, 300041, Romania; +40-256204400; cecs@umft.ro), ref: 54/04.11.2024

Study design
Interventional randomized single-blinded clinical trial with 3 months follow-up

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
Severe and advanced periodontitis

Interventions
Participants will be randomly assigned to one of three groups: test group 1 will receive treatment with hyaluronic acid and hypochlorite gel; test group 2 will use hypochlorite gel alone, and group 3 (control) will receive a placebo gel.
Subgingival instrumentation will be performed under local anesthesia using ultrasonic and manual instruments, with protocol-specific gel applications preceding the instrumentation.
Three months post-treatment, participants will undergo reevaluation of clinical, microbiological, histological and enzymatic parameters. Data will be analyzed using appropriate statistical methods.

Intervention Type
Procedure/Surgery

Primary outcome measure
Probing depth (PD) is measured using a periodontal probe (PCP-UNC 15, Hu-Friedy Manufacturing Co., Chicago, IL, USA) at baseline and 3 months post-therapy

Secondary outcome measures
1. Full mouth plaque score (FMPS) is measured using a periodontal probe (PCP-UNC 15, Hu-Friedy Manufacturing Co., Chicago, IL, USA) at baseline and 3 months post-therapy
2. Full mouth bleeding score (FMBS) is measured using a periodontal probe (PCP-UNC 15, Hu-Friedy Manufacturing Co., Chicago, IL, USA) at baseline and 3 months post-therapy
3. Clinical attachment loss (CAL) is measured using a periodontal probe (PCP-UNC 15, Hu-Friedy Manufacturing Co., Chicago, IL, USA) at baseline and 3 months post-therapy
4. Gingival recession (GR) is measured using a periodontal probe (PCP-UNC 15, Hu-Friedy Manufacturing Co., Chicago, IL, USA) at baseline and 3 months post-therapy
5. Bacterial pathogens are quantitatively evaluated using PCR testing at baseline and 3 months post-therapy from sites with the highest probing pocket depth (PPD)
6. MMP-8 and IL-1 levels are analyzed using dento-ELISA immunoassay at the University Department of Biochemistry at UMVBT from gingival crevicular fluid samples collected at baseline and 3 months post-treatment from the site with the deepest probing depth
7. Inflammatory status is assessed histologically by analyzing gingival biopsies harvested using micro-tissue punches at baseline and 3 months post-treatment to determine the amount of inflammatory cells and describe the characteristics of intercellular substance in relation to the clean and seal protocol

Overall study start date
04/11/2024

Completion date
30/07/2027

Eligibility

Key inclusion criteria
1. Adult patients aged 18 - 65 years
2. At least 10 remaining teeth in oral cavity
3. Presence of minimum 4 sites with periodontal pockets ≥5mm, with positive BOP, radiographic bone loss ≥3mm

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Molars with furcation involvement class II or III
2. Endodontic lesions
3. Severe occlusal dysfunction
4. Antibiotic treatment 3 months prior to the start of the trial or during study participation
5. Systemic diseases that may influence the outcome of periodontal therapy (e.g., uncontrolled diabetes prior to or during study participation)
6. Immunocompromised patients
7. Allergic patients to NaOCl
8. Pregnant and breastfeeding women

Date of first enrolment
15/11/2024

Date of final enrolment
01/01/2027

Locations

Countries of recruitment
Romania

Study participating centre
University Clinic of Periodontology, Victor Babes University of Medicine Timisoara
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Sponsor information

Organisation
Victor Babeș University of Medicine and Pharmacy Timișoara

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Sponsor type
University/education

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Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

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

Intention to publish date
01/10/2027

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be available upon request from Dr Elena Catana, elena.catana@umft.ro

IPD sharing plan summary
Available on request