

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 29/11/2024	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 29/11/2024	Condition category Oral Health	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

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 Babeş 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

Contact name

Dr Elena Catana

ORCID ID

<https://orcid.org/0009-0009-2711-7691>

Contact details

Str. Martir Constantin Valceanu nr.18
Timișoara
Romania
300291
+40 745649445
elena.catana@umft.ro

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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 UMBVT 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

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 $\geq 5\text{mm}$, with positive BOP, radiographic bone loss $\geq 3\text{mm}$

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

65 years

Sex

All

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

9, Bv. Revolutiei din 1989

Timisoara

Romania

300041

Sponsor information

Organisation

Victor Babeş 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 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