ISRCTN15664098 https://doi.org/10.1186/ISRCTN15664098

Evaluation of the response to a protocol of treatment for severe periodontitis using subgingival instrumentation plus a combination of sodium hypochlorite and hyaluronic acid

Submission date
23/11/2024

Recruitment status
Recruiting

Registration date
29/11/2024

Overall study status
Ongoing

Last Edited
29/11/2024

Condition category
Oral Health

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
This study aims to evaluate the impact of incorporating hyaluronic acid into the Clean&Seal® protocol compared to a sodium hypochlorite gel alone and a placebo, during the repeated subgingival instrumentation for severe periodontitis. This study has received ethical approval from the Victor Babeș University of Medicine and Pharmacy, Timișoara.

Who can participate?
Adult participants, who completed the first and the second step of periodontal therapy, with at least 10 remaining teeth in the mouth, the presence of a minimum of 4 sites with moderate periodontal pockets of 4-5mm at the re-evaluation, with bleeding on probing, radiographic bone loss ≥3mm

What does the study involve?
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.

What are the possible benefits and risks of participating?
Possible benefits for the patient include: improved periodontal health through more effective subgingival re-instrumentation, enhanced clinical outcomes by reducing bacterial load, tissue repair and improved overall gum health.

Possible risks include: mild to moderate irritation or sensitivity during or after treatment due to the chemical agents, risk of allergic reactions to the components of the gel.

Where is the study run from?
The University Clinic of Periodontology, Victor Babes University of Medicine Timisoara.

When is the study starting and how long is it expected to run for?
September 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
Timisoara
Romania
300291
+40 (0)745649445
elena.catana@umft.ro

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CE-2-2024

Study information

Scientific Title
Clinical, microbiological, histological and enzymatic evaluation of hyaluronic acid used in the Clean&Seal® protocol, at step 3 of therapy in the non-surgical treatment of stage III and IV periodontitis

Acronym

C&S-STEP3

Study objectives
Clean&seal protocol in re-instrumentation in step 3 of periodontal treatment results in better clinical, microbiological, enzymatic and histological 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 (0) 256204400; cecs@umft.ro), ref: 55/04.11.2024

Study design
Randomized single-blind 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
Subgingival re-instrumentation with adjunctive sodium hypochlorite gel and hyaluronic acid

For each participant will be recorded age, gender, smoking status, and presence/absence of a well-controlled diabetes mellitus. Baseline assessments will measure clinical parameters such as probing depth full mouth plaque score (FMPS), full mouth bleeding score (FMBS), clinical attachment level (CAL), probing depth (PD), and gingival recession (GR). Additional evaluations will include microbiological analysis of periodontal pathogens: Aggregatibacter actinomycetemcomitans (A.a), Porphiromonas gingivalis (P.g), Prevotella intermedia (P.i), Treponema denticola (T.d), Tanerella forsythia (T.f), using PCR testing, enzymatic assays measuring inflammatory biomarkers, including matrix metalloproteinase-8 (MMP-8) and interleukin-1 (IL-1), using ELISA and histological evaluations to assess the inflammatory status.

Participants will be randomly assigned into three groups using a pre-compiled list generated with the randomization software at www.random.org: test group 1 will receive treatment with xHyA (Hyadent BG®) and Perisolv®; test group 2 will use Perisolv® alone; and a placebo group will receive a placebo gel. Subgingival instrumentation will be performed under local anesthesia using ultrasonic and manual methods, with protocol-specific gel applications preceding instrumentation. Three months post-treatment, participants will undergo re-evaluation of clinical, microbiological, histological and enzymatic parameters. Data will be analyzed using statistical methods, including Shapiro-Wilk tests for normality and appropriate paired or non-parametric tests for intra- and inter-group comparisons.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Periodontal probing depth (PPD) measured using a periodontal probe at baseline and 3 months post-therapy

Key secondary outcome(s))
1. FMPS (full mouth plaque score), FMBS (full mouth bleeding score), CAL (clinical attachment loss), PD (probing depth), GR (gingival recession) measured using a periodontal probe at baseline and 3 months post-therapy
2. Quantitative evaluation of bacterial pathogens will be performed at baseline and three months post-therapy, from sites with the highest PPD (probing pocket depth), using PCR testing
3. MMP-8 and IL-1 analysis in samples of gingival crevicular fluid collected from the site with the deepest probing depth measured using dento-ELISA immunoassay at baseline and three months post-treatment and sent to the laboratories of the University Department of Biochemistry at UMVBT
9. To histologically assess the inflammatory status, gingival biopsies will be harvested from areas posing no esthetic or functional risk using micro-tissue punches and will be analyzed at baseline and three months post-treatment, to determine the amount of inflammatory cells and to describe the characteristics of intercellular substance to the clean and seal protocol

Completion date
30/07/2027

Eligibility

Key inclusion criteria
1. Patients with stage III and IV periodontitis
2. Achieved the first and the second steps of periodontal therapy
3. At least 10 remaining teeth in the oral cavity
4. Presence of minimum 4 sites with moderate periodontal pockets 4-5 mm
5. Positive BOP
6. Radiographic bone loss ≥3 mm

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Total final enrolment
80

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 (ex. 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 Babeș 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