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Exploring the impact of antimicrobial treatments combined with dental cleaning on gum disease patients

Submission date
30/04/2025

Recruitment status
Recruiting

Registration date
21/05/2025

Overall study status
Ongoing

Last Edited
27/05/2025

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
This study aims to find out if using an antimicrobial treatment called HybenX (HY) along with standard dental cleaning (SRP) provides extra benefits for people with severe gum disease (periodontitis). Researchers will compare the results of using both treatments together versus using only the dental cleaning.

Who can participate?
Adults over 18 years old with severe gum disease (stage III or IV periodontitis), good general health, and at least five natural teeth per quadrant can participate. Participants must have at least two sites with a pocket depth greater than 4 mm.

What does the study involve?
Participants will receive a full-mouth examination (excluding wisdom teeth) at the start and after three months. In each participant, two randomly chosen sections of the mouth will be treated with both SRP and HY, while the other two sections will receive only SRP. The study will be conducted at a single center.

What are the possible benefits and risks of participating?
Participants will benefit from free complex periodontal assessment and treatment. Risks include potential allergic reactions and chemical burns from HybenX, and complications from anesthesia such as temporary loss of sensitivity, pain at the puncture site, and local hematoma. There may also be other unpredictable risks.

Where is the study run from?
Iuliu Haţieganu University of Medicine and Pharmacy (Romania)

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

Who is funding the study?
Universitatea de Medicină şi Farmacie Iuliu Haţieganu Cluj-Napoca (Romania)

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
The use of a local desiccant antimicrobial agent in periodontal therapy: a randomized clinical trial

Acronym
ULDAAPT

Study objectives
The study aimed to analyze whether there are differences in clinical efficacy by using a commercial desiccant antimicrobial agent Hybenx in combination with subgingival mechanical instrumentation (SRP) vs. SRP alone for the treatment of severe periodontitis cases during a three-month interval.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 03/12/2024, Ethics Committee of the County Emergency Hospital (str. Clinicilor nr. 3-5, Cluj-Naopca, 400006, Romania; +40 264597256; secretariat@scjucluj.ro), ref: 46170

Study design
Single center split-mouth randomized controlled clinical trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Periodontitis

Interventions

Each patient will receive an initial complete full-mouth clinical examination, excluding wisdom teeth (baseline assessment). Periodontal examinations will be performed in the clinic setting with standard equipment: dental mirror, UNC-15 periodontal probe, with millimiter markings (Hu-Friedy, Chicago, IL, USA).
Based on the evaluated clinical periodontal parameters: probing depth (PD), gingival recession (GR), clinical attachment loss (CAL), and bleeding on probing scores the diagnosis of periodontitis, will be established, according to the 2018 classification system developed by the EFP and AAP. Gingival inflammation will be assessed using the Gingival Bleeding Index (GBI), and oral hygiene will be quantified with the Oral Hygiene Index (OHI) scores.
The periodontal diagnosis will be set based on the presence of interdental CAL at a minimum of two non-adjacent teeth, or buccal /oral CAL ≥ 3 mm associated with PD > 3 mm. The identified periodontitis cases will be divided into four stages based on the severity of the periodontal tissue destruction: stage I (mild) periodontitis; stage II (moderate) periodontitis; stage III and stage IV (severe and very severe) periodontitis. Cases that do not meet periodontitis case definition criteria will be classified as either gingivitis or periodontally healthy cases.
After initial clinical periodontal assessment and diagnosis, a standard, stepwise treatment plan will be provided for each patient based on the available recommendations, including the first-step of the periodontal therapy, comprising of patient behavioral change interventions, supragingival biofilm control, and management of modifiable risk factors. Cause-related therapy consisting of mechanical subgingival instrumentation will be initiated only after the first-step therapy endpoints will be achieved. For each periodontitis patient, two hemiarches of the four hemiarches will be treated with subgingival mechanical instrumentation (SRP) plus HybenX and will be included in the test group (SRP plus HY group), while the other two hemiarches that will receive SRP alone will be included in the control group (SRP group). After completing the study, patients will receive the other therapy steps as planned.

The hemiarches (hemiarches 1 and 4) will be randomly assigned to one of the therapies (SRP plus HY or SRP alone) based on a randomization table. On the first treatment day, hemiarches 1 and 4 will be treated following random allocation (test therapy or control therapy); the following day, the other treatment will be applied for the other two hemiarches (hemiarches 2 and 3).

The records of the participants will not contain any mention of treatment allocation. The list containing allocation numbers and patient's names will be kept by the senior periodontologist, who is also responsable for patient's recruitment. The baseline examination and the treatment will be provided by two investigators, and re-evaluations will be performed by other investigators. Investigators conducting the follow-up examination and the statistician will not be aware of the treatment type received by patients.
HybenX application protocol according to the manufacturer:
• Dry the tooth
• Apply HybenX® via cannula before scaling and root planing in pockets deeper than 5 mm.
• Wait 10–30 seconds
• Remove HybenX® with supragingival and subgingival to the base of periodontal pockets suction and rinse with water until clear

Intervention Type
Device

Phase
Phase III/IV

Drug/device/biological/vaccine name(s)

Hybenx (a concentrated mixture of acidified phenolics, a desiccating agent, consisting of 60% sulfonated phenolics, 28% sulfuric acid, and 12% water)

Primary outcome(s)
Measured at baseline and follow up:
1. Probing depth (PD) is measured using a periodontal probe at six sites per tooth
2. Gingival recession (GR) is measured using a periodontal probe at six sites per tooth
3. Clinical attachment loss (CAL) is measured using a periodontal probe at six sites per tooth
4. Gingival Bleeding Index (GBI) is measured using the presence of bleeding upon probing at four sites per tooth and calculated as a percentage of bleeding sites over total sites
5. Oral Hygiene Index (IHI) is measured using the presence of visible dental plaque at four sites per tooth and calculated as a percentage of plaque-positive sites over total sites
6. Change in total probing depth (PD) is measured using a periodontal probe at six sites per tooth and compared between intervention groups

Key secondary outcome(s))
Measured at baseline and follow up:
1. Total probing depth (PD) is measured using a periodontal probe at six sites per tooth, calculating the average of all sites evaluated
2. Interproximal probing depth (PD) is measured using a periodontal probe at six sites per tooth, calculating the average of interproximal sites evaluated
3. Total clinical attachment loss (CAL) is measured using a periodontal probe at six sites per tooth, calculating the average of all sites evaluated
4. Interproximal clinical attachment loss (CAL) is measured using a periodontal probe at six sites per tooth, calculating the average of interproximal sites evaluated
5. Count of total probing depths equal to 5 mm is measured using a periodontal probe at six sites per tooth, summing the number of sites with PD = 5 mm
6. Count of interproximal probing depths equal to 5 mm is measured using a periodontal probe at six sites per tooth, summing the number of interproximal sites with PD = 5 mm
7. Count of total probing depths greater than or equal to 6 mm is measured using a periodontal probe at six sites per tooth, summing the number of sites with PD ≥ 6 mm
8. Count of interproximal probing depths greater than or equal to 6 mm is measured using a periodontal probe at six sites per tooth, summing the number of interproximal sites with PD ≥ 6 mm
9. Oral Hygiene Index (IHI) score is measured using a dental plaque detector at four sites per tooth, calculated as the percentage of plaque-positive sites over total sites
10. Gingival Bleeding Index (GBI) score is measured using a periodontal probe at four sites per tooth, calculated as the percentage of bleeding sites over total sites

Completion date
01/10/2027

Eligibility

Key inclusion criteria
1. Periodontitis stage III-IV
2. Good systemic health
3. Age>18 years
4. Minimum 5 natural teeth per quadrant
5. A minimum of 2 sites on different teeth with a pocket probing depth (PD)>4 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. Periodontal and/or antibiotic therapy within the last 6 months
2. Use of antiseptic mouthwashes in the last 3 months
3. Pregnancy
4. Severe systemic conditions
5. Immunosuppressive therapy/current radiotherapy

Date of first enrolment
12/12/2024

Date of final enrolment
01/10/2026

Locations

Countries of recruitment
Romania

Study participating centre
Periodontology Outpatient Clinic, University of Medicine and Pharmacy "Iuliu Haţieganu", Cluj-Napoca
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Sponsor information

Organisation
Iuliu Haţieganu University of Medicine and Pharmacy

ROR
https://ror.org/051h0cw83

Funder(s)

Funder type
University/education

Funder Name
Universitatea de Medicină şi Farmacie Iuliu Haţieganu Cluj-Napoca

Alternative Name(s)
University of Medicine and Pharmacy Cluj-Napoca, Iuliu Haţieganu University of Medicine and Pharmacy, University of Medicine and Pharmacy "Iuliu Haţieganu" Cluj-Napoca, “Iuliu Hatieganu” University of Medicine and Pharmacy Cluj-Napoca, Universitatea de Medicină și Farmacie “Iuliu Haţieganu”, UMF Iuliu Haţieganu Cluj-Napoca, UMF Cluj, UMF Cluj-Napoca, UMFCLUJ, UMF

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Romania

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from: Costin Iulia Roxana (Maniac-Costin), email address: costiniuliaroxana@yahoo.com

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	in Romanian		21/05/2025	No	Yes
Participant information sheet	in Romanian		21/05/2025	No	Yes