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Effectiveness of 0.2% hyaluronic acid on clinical, biomolecular and microbiological parameters in type 2 diabetes mellitus patients with periodontitis: a randomized clinical trial

Submission date
28/03/2024

Recruitment status
No longer recruiting

Registration date
09/04/2024

Overall study status
Completed

Last Edited
24/06/2025

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
We want to see if using 0.2% hyaluronic acid (HA) gel alongside regular dental treatment can help diabetic patients heal faster after a specific dental procedure called scaling and root planing (SRP). This study aims to check if applying the HA gel can make improvements in various aspects of gum health, including reducing harmful bacteria like Pg and Fn, and balancing levels of inflammatory substances like IL-1β and IL-10 in diabetic patients who have gum disease.

Who can participate?
Any participant aged 40-65 years, with periodontitis and an HbA1c test result is included.

What does the study involve?
The study involves a thorough evaluation that includes measuring various clinical indicators and collecting samples from the gums and teeth. Our treatment plan consists of a dental procedure called scaling and root planing (SRP) along with an additional therapy. Participants will be divided into two groups: the test group will receive a 0.2% hyaluronic acid gel after scaling, while the control group will get a placebo gel. Importantly, the individuals administering the gel will not know which type it is, ensuring a rigorous double-blind setup. After the initial treatment, participants will return for a follow-up visit four weeks later for further assessments, including more measurements and sample collection.

What are the possible benefits and risks of participating?
Taking part in this study can help improve your oral hygiene and overall health by undergoing scaling and root planing, which are important dental procedures. Moreover, maintaining good gum health has been linked to lower blood sugar levels in diabetic individuals. We are also investigating the possible advantages of hyaluronic acid, which is known for its ability to promote healing, in speeding up recovery after scaling and root planing. However, it's essential to be aware of potential risks, such as slower healing, particularly for diabetic patients, and the chance of allergic reactions to the gel used in the treatment.

Where is the study run from?
Universitas Indonesia (Indonesia)

When is the study starting and how long is it expected to run for?
December 2022 to October 2023

Who is funding the study?
Research and Development Directorates of Universitas Indonesia of the 2023 PUTI Q2 grant (grant number:NKB-1277/UN2.RST/HKP.05.00/2022)

Who is the main contact?
Prof Sri Lelyati Masulili, srilelyati@yahoo.com

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
090660722

Study information

Scientific Title

The aim of this research is to assess the effectiveness of 0.2% HA gel on periodontal parameter, quantity of Pg and Fn, and the levels of proinflammatory cytokine, IL-1β, and anti-inflammatory cytokine, IL-10, in type 2 DM patients with periodontitis

Study objectives
Use of adjunctive hyaluronic acid 0.2% gel significantly improves clinical, biomolecular and microbiological parameters of periodontitis in DM patients.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 09/12/2022, Ethical Commission for Dental Research, Faculty of Dentistry, Universitas Indonesia (Jl. Salemba Raya Jl. Salemba Raya IV No.2, RT.2/RW.5, Kenari, Kec. Senen, Kota Jakarta Pusat, Daerah Khusus Ibukota, Jakarta, 10430, Indonesia; +62 2131906289; etikrisetfkg@ui.ac.id), ref: 130 /Ethical Approval /FKGUI/XII/2022

Study design
Interventional parallel double-blind randomized clinical trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Periodontitis with diabetes mellitus

Interventions
This research design is a parallel, double-blind, placebo-controlled randomized controlled trial. Subjects consist of two groups: the non-DM group and the DMT2 group. Subsequently, each group will be randomly divided into test and control groups, with the test groups receiving hyaluronic acid 0.2% gel and the control group receiving a placebo gel.

During the first visit, patients will receive an explanation about the research, fill out a screening form, submit their HbA1c test levels, and sign an informed consent to participate. All participants will then undergo clinical parameter examinations of BoP (Bleeding on Probing), PPD (Probing Pocket Depth), and CAL (Clinical Attachment Level). using a UNC-15 probe (Hu-Friedy, USA), as well as subgingival plaque and GCF sampling using sterilized no. 25 paper points (Gapadent, China). Following this, scaling and root planing will be performed, and participants will randomly receive either hyaluronic acid gel or placebo gel. Both gels will be inserted into a 1cc syringe with a special tip that is identical and randomly coded by the Pharmacy Faculty of the University of Indonesia (UI FK), ensuring that the operator is unaware of the composition of the syringe. Patients will also receive oral hygiene education, instructions, and identical toothbrushes and toothpaste to use during the research period.

The follow-up visit is scheduled for 4 weeks after the first visit, during which participants will undergo clinical parameter examinations of BoP, PPD, and CAL, and collection of subgingival plaque and GCF samples, without receiving any additional treatment.

Plaque samples will be processed in the laboratory using RT-PCR equipment with 16S rRNA sequencing method using 2-ΔΔCT to demonstrate changes in bacterial abundance in the test group compared to the control group and to obtain the quantity of Pg and Fn. GCF samples will be processed in the laboratory using the ELISA test to observe changes in the levels of IL-1 and IL-10 cytokines and will be statistically analyzed using SPSS Version 26.0.

Intervention Type
Other

Primary outcome(s)
At baseline and during the 4-week follow-up using clinical examination:
1. Bleeding on probing
2. Clinical attachment loss
3. Pocket probing depth

Key secondary outcome(s))
Quantity of Pg and Fn, and the levels of proinflammatory cytokine, IL-1β, and anti-inflammatory cytokine, IL-10, obtained from the analysis of subgingival plaque and GCF samples collected at baseline and during the 4-week follow-up period.

Completion date
27/10/2023

Eligibility

Key inclusion criteria
1. Age range of 40 to 65 years.
2. Diagnosed with periodontitis according to European Federation of Periodontology (EFP)
3. DM participants are required to obtain medical clearance for SRP treatment.
4. Participants are willing to participate in research and have signed an informed consent

Participant type(s)
Patient, Population

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
40 years

Upper age limit
65 years

Sex
All

Total final enrolment

Key exclusion criteria
1. Participants who regularly use medications known to affect microbes, including antibiotics, anti-inflammatory drugs, immunosuppressive drugs, bisphosphonates, and blood thinners
2. Individuals with bleeding disorders, mental disorders, and acute infections
3. Individuals who have received periodontal therapy within the past six months
4. Individuals that are allergic to HA gel
5. Pregnant or breastfeeding women

Date of first enrolment
06/03/2023

Date of final enrolment
26/05/2023

Locations

Countries of recruitment
Indonesia

Study participating centre
Rumah Sakit Khusus Gigi dan Mulut, Fakultas Kedokteran Gigi, Universitas Indonesia
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Sponsor information

Organisation
University of Indonesia

ROR
https://ror.org/0116zj450

Funder(s)

Funder type
University/education

Funder Name
Research and Development Directorates of Universitas Indonesia of the 2023 PUTI Q2 grant

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to patient confidentiality.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		29/07/2024	24/06/2025	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes