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Testing simvastatin and hyaluronic acid gel to help dental implants heal and enhance their stability

Submission date 13/05/2025	**Recruitment status** Recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 16/05/2025	**Overall study status** Ongoing	
Last Edited 27/08/2025	**Condition category** Oral Health	

Plain English summary of protocol

Background and study aims
This study is looking at ways to help dental implants heal better and stay in place more securely. Researchers are testing whether applying hyaluronic acid gel (a substance naturally found in the body) and simvastatin (a common medicine used to lower cholesterol) at the implant site can improve healing and stability.

Who can participate?
People who need dental implants and meet certain health criteria may be able to take part. Some individuals, such as those with certain medical conditions or habits like smoking, may not be eligible.

What does the study involve? (for participants)
A total of 32 participants will be divided into four groups:
-One group will receive no special treatment (control group).
-One group will have hyaluronic acid gel applied to the implant site.
-One group will receive simvastatin.
-One group will get both hyaluronic acid and simvastatin.
Researchers will check how stable the implants are right after placement, then again at 40 days and 60 days.

What are the possible benefits and risks of participating?
Participants may benefit from improved healing of their dental implants. However, as with any medical study, there may be some risks, such as side effects or reactions to the treatments. All participants will be monitored closely.

Where is the study run from?
University of Suleimani (Iraq)

When is the study starting and how long is it expected to run for?
July 2024 to September 2025

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Ahmed Mohammed, ahmed.darweesh@univsul.edu.iq

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
Dr Ahmed Mohammed

ORCID ID
https://orcid.org/0009-0008-2759-5610

Contact details
Al-Shorja Street
Kirkuk
Iraq
36001
+964 7701688495
ahmed.darweesh@univsul.edu.iq

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Evaluation of the effect of hyaluronic acid gel and simvastatin on dental implant stability

Study objectives
The null hypothesis to be tested is:
The application of hyaluronic acid gel and simvastatin does not result in a statistically significant improvement in bone regeneration and implant stability compared to the use of either agent alone or conventional methods.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 16/12/2024, Ethical Committee of the College of Dentistry, University of Sulaimani (College of Dentistry, University of Sulaimani, Madam Mitterrand street, As Sulaymaniyah, Iraq, Sulaymaniyah, 46001, Iraq; +964 7704522890; dentistry.ethics@univsul.edu.iq), ref: COD-EC-24-0048

Study design
Prospective interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
University/medical school/dental school

Study type(s)
Efficacy

Participant information sheet
See trial outputs table

Health condition(s) or problem(s) studied
Promoting dental implant stability in edentulous adults

Interventions
This is a randomized, controlled clinical trial including 32 dental implants placed in medically healthy adult patients (18–60 years old), divided equally into four groups (n = 8 implants/group).

Group 1 – Control Group
Treatment: No adjunctive material.
Administration: Standard implant placement following conventional osteotomy preparation.
Duration: Implant placed at baseline.
Follow-up: ISQ measured immediately post-op, at 40 days, and at 60 days.
Total Follow-up: 60 days.

Group 2 – Hyaluronic Acid (HA) Group
Treatment: Hyaluronic acid gel.
Dose: 0.1 ml of hyaluronic acid gel per osteotomy site.
Administration: HA gel is injected directly into the osteotomy site before implant placement.
Duration: Single administration at baseline.
Follow-up: ISQ measured at baseline, 40 days, and 60 days.
Total Follow-up: 60 days.

Group 3 – Simvastatin Gel Group
Treatment: Simvastatin prepared in gel form.

Dose: 0.1 ml of simvastatin gel per osteotomy site.
Administration: The gel is inserted into the osteotomy site just before implant placement.
Duration: Single administration at baseline.
Follow-up: ISQ measured at baseline, 40 days, and 60 days.
Total Follow-up: 60 days.

Group 4 – Combination Group (Simvastatin + Hyaluronic Acid)
Treatment: A mixture of simvastatin gel and hyaluronic acid gel.
Dose: 0.1 ml of the combined gel (containing both agents) per osteotomy site.
Administration: The mixture is inserted into the osteotomy site immediately before implant placement.
Duration: Single administration at baseline.
Follow-up: ISQ measured at baseline, 40 days, and 60 days.
Total Follow-up: 60 days.

Randomization Process
Patients are randomly allocated to one of the four groups using a sealed opaque envelope technique. Allocation is performed by an independent third party to ensure allocation concealment and reduce selection bias.

Intervention Type
Other

Primary outcome measure
Implant Stability Quotient (ISQ) values measured at three time points (immediate, 40 days, and 60 days post-implantation) using resonance frequency analysis.

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
05/07/2024

Completion date
30/09/2025

Eligibility

Key inclusion criteria
1. Patients aged 18–60 years with missing teeth.
2. Systemically healthy individuals.
3. Patients with bone density D3 at the site of implant placement.
4. Presence of adequate bone height minimum of 10 mm above the anatomical landmarks and adequate width, so that 1.5–2 mm of bone is present all around the implants after implant placement.
5. Bone crest healing period of more than 3 months before implant placement.
6. Good oral hygiene and compliance with follow-up appointments.
7. No known allergies to simvastatin or hyaluronic acid.

Participant type(s)
Healthy volunteer, Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
60 Years

Sex
Both

Target number of participants
32 dental implants

Key exclusion criteria
1. Patients with uncontrolled systemic diseases.
2. Patients who are chronic smokers.
3. Pregnant and lactating women.
4. Patients with a history of chemotherapy or radiotherapy in the last 6 months.
5. Patients with blood dyscrasias.
6. Patients with parafunctional habits like bruxism.
7. Patients with poor oral hygiene and untreated periodontal disease.
8. Patients with a history of allergy to SMV or HA.
9. Alcoholic patients or alcohol users.
10. Patients with active liver disease and those on Warfarin and/or antifungal medication.

Date of first enrolment
10/01/2025

Date of final enrolment
30/09/2025

Locations

Countries of recruitment
Iraq

Study participating centre
University of Suleimani
College of Dentistry, Madam Mitterrand street
Sulaymaniyah
Iraq
46001

Sponsor information

Organisation
University of Sulaimani

Sponsor details
College of Dentistry, Madam Mitterrand, Sulaymaniyah, Iraq
Sulaymaniyah
Iraq
46001
+964 7725447528
pg.dent@univsul.edu.iq

Sponsor type
University/education

Website
https://dent.univsul.edu.iq

ROR
https://ror.org/00saanr69

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
01/02/2026

Individual participant data (IPD) sharing plan
At the end of the study, anonymized individual participant data (IPD) may be shared upon reasonable request for research or academic purposes. Data will be de-identified to protect participant privacy and confidentiality. Requests must be submitted to the chief investigator and approved by the ethics committee. The data will only be shared under a data-sharing agreement that ensures proper use.
contact info;

Name: AHMED JAMEEL MOHAMMED DARWEESH
Email: ahmed.darweesh@univsul.edu.iq

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	in Arabic		15/05/2025	No	Yes
Participant information sheet	in English		15/05/2025	No	Yes
Participant information sheet	in Kurdish		15/05/2025	No	Yes