

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

<b>Submission date</b> 13/05/2025	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 16/05/2025	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 08/12/2025	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## 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

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Protocol serial number

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

## **Study type(s)**

Efficacy

## **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(s)

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

#### Key secondary outcome(s)

There are no secondary outcome measures

#### Completion date

18/09/2025

## 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)

Patient

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Lower age limit

18 years

#### Upper age limit

60 years

#### Sex

All

### **Total final enrolment**

32

### **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**

20/07/2025

## **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

### **ROR**

<https://ror.org/00saanr69>

# Funder(s)

## Funder type

Other

## Funder Name

Investigator initiated and funded

# Results and Publications

## 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;

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## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	in Arabic		15/05/2025	No	Yes
<a href="#">Participant information sheet</a>	in English		15/05/2025	No	Yes
<a href="#">Participant information sheet</a>	in Kurdish		15/05/2025	No	Yes