

# Testing a new type of dental implant for people with severe bone loss in the upper back jaw

<b>Submission date</b> 07/06/2025	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 11/06/2025	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 11/06/2025	<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 exploring a new way to help people who have lost a lot of bone in the back part of their upper jaw. Normally, these patients would need a complex surgery called a sinus lift before getting dental implants. This study is testing a different approach using special implants called pterygoid and compressive implants, which can be placed right away without the need for that surgery. The researchers want to see how successful this method is after one year, how much pain it causes, and whether it affects the health of the gums.

### Who can participate?

People can take part in the study if they have at least 4 mm of bone width in the premolar area of their upper jaw, and if a specific part of their sinus is located in front of the second premolar.

### What does the study involve?

Participants will receive dental implants under local anesthesia. The dentist will make a small cut in the gum, place the implants in the premolar and pterygoid areas, and then stitch the area closed. The implants must be placed with a certain amount of pressure to be included in the study. The researchers will follow up with participants for one year to check how well the implants are working, how much pain they experience, and how their gums respond.

### What are the possible benefits and risks of participating?

The main benefit is that participants may receive a full set of upper teeth without needing more invasive surgery. However, as with any dental procedure, there are risks such as pain, swelling, or implant failure. The study will monitor these closely.

### Where is the study run from?

Damascus University (Syria)

### When is the study starting and how long is it expected to run for?

September 2022 to September 2025.

### Who is funding the study?

Investigator initiated and funded

Who is the main contact?  
Professor Mazen Zenati, mazenzenati@gmail.com

## Contact information

### Type(s)

Public, Scientific, Principal investigator

### Contact name

Prof Mazen Zenati

### Contact details

Damascus city  
Damascus  
Syria  
014796  
+963 933348895  
mazenzenati@gmail.com

## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

Nil known

## Study information

### Scientific Title

Evaluation of Immediate Loading Using Multi Units compressive and pterygoid one piece implants with severe posterior maxillary atrophy

### Study objectives

1. Pterygoid implants will be sufficient and successful.
2. Pterygoid implants will serve as an alternative to external sinus lifts.

### Ethics approval required

Ethics approval required

### Ethics approval(s)

approved 22/04/2025, Scientific Research and Postgraduate Studies Council (Baramkeh, Damascus, 00258, Syria; +963 1133923192; ap.srd@damascusuniversity.edu.sy), ref: DN-150425-H25

### Study design

Interventional with one group (before-and-after study) no control group one-center study and single-blinded (statistician)

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Severe bone deficiency in the posterior region of the maxilla

### **Interventions**

The participants will be treated under local anesthesia by using lidocaine with epinephrine 1:80,000. An incision will be made along the crest, and a full-thickness flap will be elevated. Implants will be placed in the premolars and pterygoid regions. Pterygoid and premolar implants should attain an insertion torque of at least 45 Ncm to be included in the study. Suture the incision using 4/0 nylon sutures with a reversed cutting needle.

### **Intervention Type**

Procedure/Surgery

### **Primary outcome(s)**

1. Insertion torque using ratchet (at baseline)
2. Pain levels using VAS (daily in the first 7 days)
3. Plaque Score and Gingival Index using Periodontal probe (after 7 days, 3 months, 6 months, 9 months, and 12 months)

### **Key secondary outcome(s)**

Implant success after one year using a periodontal probe

### **Completion date**

01/09/2025

## **Eligibility**

### **Key inclusion criteria**

1. Presence of bone width 4 mm in premolar area.
2. Inferior corner of the anterior wall of the sinus positioned anterior to the second premolar.

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

**Upper age limit**

70 years

**Sex**

All

**Total final enrolment**

20

**Key exclusion criteria**

1. Patients with bruxism and/or clenching.
2. Presence of systemic uncontrolled diseases that could represent a general contraindication to put implants.
3. Ongoing maxillary radiation therapy.
4. Active chemotherapy.

**Date of first enrolment**

01/01/2023

**Date of final enrolment**

01/01/2025

## **Locations**

**Countries of recruitment**

Syria

**Study participating centre**

**Damascus University**

Fayez Mansour st, Almazzah

Damascus

Syria

11259

## **Sponsor information**

**Organisation**

Damascus University

**ROR**

<https://ror.org/03m098d13>

# Funder(s)

## Funder type

Other

## Funder Name

Investigator initiated and funded

# Results and Publications

## Individual participant data (IPD) sharing plan

The datasets generated and analysed during the current study will be publish in the results of the study.

## IPD sharing plan summary

Published as a supplement to the results publication

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes