

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

Submission date 07/06/2025	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 11/06/2025	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 11/06/2025	Condition category 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

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Secondary study design

Non randomised study

Study setting(s)

Hospital, University/medical school/dental school

Study type(s)

Treatment

Participant information sheet

No participant information sheet available

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 measure

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)

Secondary outcome measures

Implant success after one year using a periodontal probe

Overall study start date

01/09/2022

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

Age group

Adult

Lower age limit

18 Years

Upper age limit

70 Years

Sex

Both

Target number of participants

20

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

Sponsor details

Almazzeh

Damascus

Syria

0036985

+963 1133923192

dl.srd@damascusuniversity.edu.sy

Sponsor type

University/education

Website

<http://www.damascusuniversity.edu.sy>

ROR

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

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Planned to publish in peer-reviewed journals.

Intention to publish date

01/09/2025

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