

Using platelet-rich fibrin prepared with titanium tubes in external sinus lift

Submission date 08/05/2025	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 09/05/2025	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 27/05/2025	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 aims to evaluate the effectiveness of a material called T-PRF as a solo filler in sinus lifting procedures. The goal is to compare T-PRF to traditional bone grafts (allografts and xenografts) when placing dental implants either at the same time as the sinus lift or after a delay.

Who can participate?

Participants should be in good oral health, have missing teeth in the upper jaw (premolars or molars), and meet specific bone height and width requirements. They should be aged between 30 and 60 years.

What does the study involve?

Participants will be divided into four groups:

1. Two groups will have a sinus lift and dental implant placed at the same time. One group will use T-PRF, and the other will use traditional bone grafts.
2. Two groups will have a sinus lift first and the dental implant placed after six months. One group will use T-PRF, and the other will use traditional bone grafts.

What are the possible benefits and risks of participating?

The potential benefits include gaining bone and support for dental implants in a safe, easy, and cost-effective way. There are no known risks associated with this technique.

Where is the study run from?

Damascus University (Syria)

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

September 2023 to February 2025

Who is funding the study?

Damascus University (Syria)

Who is the main contact?

Dr Zakaria Awad, awadzakaria31@gmail.com

Contact information

Type(s)

Public, Principal Investigator

Contact name

Dr Zakaria Awad

ORCID ID

<https://orcid.org/0000-0002-1190-9151>

Contact details

Faculty of Dentistry

Damascus

Syria

-

+963 964314346

zakaria31.awad@damascusuniversity.edu.sy

Type(s)

Scientific

Contact name

Prof Zaven Karabet

Contact details

Faculty of Dentistry

Damascus

Syria

-

+963 944594323

zavengarabed@damascusuniversity.edu.sy

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Nil known

Study information

Scientific Title

The use of titanium-prepared platelet-rich fibrin in sinus lifting with simultaneous and delayed implantation comparative clinical radiographic study

Acronym

T-PRF lateral window approach

Study objectives

Using T-PRF instead of bone grafts in sinus augmentation because of there are disadvantages related with bone grafts like infection, transmitting diseases, high economic cost, immune response, length period of its absorption

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 15/04/2025, Ethical Approval for Biomedical Researches (Damascus University, Damascus, -, Syria; +963 964314346; dl.srd@damascusuniversity.edu.sy), ref: DN-150425-425

Study design

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)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Bone gain to dental implants placement

Interventions

The study includes 4 groups

2 groups sinus lift with simultaneous implant placement, experimental group we use T-PRF as solo filler, control group we use allograft + xenograft

2 groups sinus lift with delayed implant placement, experimental group we use T-PRF, control group we use allograft + xenograft and implant placement after 6 months of surgery

Intervention Type

Procedure/Surgery

Primary outcome measure

1. Bone gain height is measured using CBCT imaging at baseline and 6 months
2. Bone gain volume is measured using CBCT imaging at baseline and 6 months

3. Implant stability (ISQ) is measured using MegaISQ II (RAF) at immediate implantation, 3 months, and 6 months
4. Bone density (HU) is measured using CBCT imaging at immediate post-surgery and 6 months
5. Complications (membrane perforation, sinusitis) measured using patient records

Secondary outcome measures

There are no secondary outcome measures

Overall study start date

15/09/2023

Completion date

22/02/2025

Eligibility

Key inclusion criteria

1. Good oral health
2. Have missing teeth in the premolars or molars of maxillary
3. Residual bone height between 4-6 mm for first two groups and less than 4 mm for second two groups
4. Minimum width (buccal-palatal) 6mm
5. Aged between 30-60 years

Participant type(s)

Patient

Age group

Adult

Lower age limit

30 Years

Upper age limit

60 Years

Sex

Both

Target number of participants

28 cases of sinus lift divided into 4 groups , 7 cases in each group

Key exclusion criteria

1. Systematic disease(diabetes-hyperthyroidism)
2. Contraindication of surgery
3. Patient refuses treatment
4. Bad oral health

Date of first enrolment

01/01/2024

Date of final enrolment

15/02/2025

Locations

Countries of recruitment

Syria

Study participating centre

Damascus University

Faculty of Dentistry

Damascus

Syria

-

Sponsor information

Organisation

Damascus University

Sponsor details

Faculty of Dentistry

Damascus

Syria

-

+963 944594323

zavengarabed@damascusuniversity.edu.sy

Sponsor type

University/education

Website

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

ROR

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

Funder(s)

Funder type

University/education

Funder Name

Damascus University

Alternative Name(s)

University of Damascus, , DU

Funding Body Type

Government organisation

Funding Body Subtype

Universities (academic only)

Location

Syria

Results and Publications

Publication and dissemination plan

Planned publication in a peer-reviewed journal

Intention to publish date

20/06/2025

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

awadzakaria31@gmail.com

IPD sharing plan summary

Available on request