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

Submission date 08/05/2025	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 09/05/2025	**Overall study status** Completed	
Last Edited 27/05/2025	**Condition category** Oral Health	

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?
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Contact information

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Public, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Treatment

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 s 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(s)
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

Key secondary outcome(s))
There are no secondary outcome measures

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
30 years

Upper age limit
60 years

Sex
All

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
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Sponsor information

Organisation
Damascus University

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

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