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The utilization of a mixture containing platelet-rich fibrin and Synthetic Hydroxyapatite (Nanobone) substance in the process of enhancing the volume of the maxillary sinus for medical purposes.

Submission date
10/03/2024

Recruitment status
No longer recruiting

Registration date
18/03/2024

Overall study status
Completed

Last Edited
25/07/2024

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Several techniques have been described for maxillary sinus graft augmentation such as the lateral window technique, or crestal approach with osteotomes or osseodensification. Platelet-rich fibrin (PRF) has been used in maxillary sinus lift procedures due to its ability to fasten the soft and hard tissue healing. PRF is an autologous platelet concentrate containing leukocyte. This study aims to evaluate the potential of PRF in combination with Synthetic hydroxyapatite Nanobone ® to enhance bone regeneration in sinus floor elevation with Lateral window technique in a split-mouth study, twelve sinus graft surgeries were carried out.

Who can participate?
Adults over the age of 18 years who attend consultation in University Institute of Health Sciences -IUCS in Portugal.

What does the study involve? (for participants)
Participants are asked to join this study in the implant consultation in Cespu University dental clinic . Participants must pass the screening the inclusion criteria. Participants must have pneumatized sinus with insufficient bone height for implant placement. Those in the first group as asked to give blood at the usual donation intervals (based on their gender). The study will last 6 months. Participants also complete informed consent and questionnaires before being choosen to participate in the study.

What are the possible benefits and risks of participating?
Potential faster bone and soft tissue healing using PRF

Where is the study run from?
University Institute of Health Sciences -IUCS Portugal in Cespu university dental clinic and Coimbra University Hard tissue Laboratory.

When is the study starting and how long is it expected to run for?
January 2023 to December 2023

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Clinical application of platelet-rich fibrin mixed with Synthetic Hydroxyapatite (Nanobone) material in maxillary sinus augmentation - randomised clinical trial

Study objectives
The aim of this clinical-histological study is to evaluate the potential of PRF in combination with Synthetic hydroxyapatite Nanobone to enhance bone regeneration in sinus floor elevation with Lateral window technique.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 14/07/2023, CESPU Ethics Committee (Rua Central de Gandra, Gandra, 4585-116, Portugal; +351 224 157 100; sec.ce@cespu.pt), ref: CE/IUCS/CESPU-18/23

Study design
Interventional randomized controlled (split-mouth) trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Reduced bone height in the posterior maxilla (1-4 mm)

Interventions
Participants will be randomized to test or control treatment lateral window technique for sinus augmentation using Liquid PRF with Nanobone / Nanobone alone based on computer-generated random codes. The allocation will be hidden from the surgeon by opaque envelopes to be opened right before the surgical procedure. With the exception of the surgical technique used, all methodology will be similar for both groups. Patients will be followed up for 6 months after surgery and until the implants are loaded with the final restoration.

Intervention Type
Procedure/Surgery

Primary outcome measure
Pain perception measured using the Visual Analogue Scale during the first week after surgery

Secondary outcome measures
1. Quality of life measured using the Oral Health Impact Profile 14 translated in Portuguese during the first week after surgery

2. Implant osseointegration success rate measured using clinical examination at 6 months after surgery
3. Patient registration of analgesic medication usage during the first week after surgery

Overall study start date
02/01/2023

Completion date
17/12/2023

Eligibility

Key inclusion criteria
1. At least eighteen years old
2. Have healed edentulous sites on the posterior maxillae region with 5mm or less residual bone height to place implants in need of sinus graft procedure.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
60 Years

Sex
Both

Target number of participants
50

Total final enrolment
6

Key exclusion criteria
1. Alcoholism
2. Smoking
3. Drug abuse
4. Diabetes
5. Heart disease
6. Bleeding disorders
7. Weakened immune systems
8. Radiation exposure
9. Bleeding disorders
10. Past or ongoing use of steroids or bisphosphonates
11. Prior bone augmentation

Date of first enrolment
15/07/2023

Date of final enrolment
28/07/2023

Locations

Countries of recruitment
Portugal

Study participating centre
University Institute of Health Sciences -IUCS
Rua Central de Gandra
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Sponsor information

Organisation
SUAVEMED

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Sponsor type
Other

Website
https://www.suavemed.pt/

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in 2024, in a high-impact peer-reviewed journal in an ongoing study of the histological results.

Intention to publish date
01/08/2024

Individual participant data (IPD) sharing plan
The data will be stored in the IUCS-CESPU repository named Repositório CESPU (https://repositorio.cespu.pt/)

IPD sharing plan summary
Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			18/03/2024	No	Yes
Results article		25/07/2024	25/07/2024	Yes	No