ISRCTN99349253 https://doi.org/10.1186/ISRCTN99349253

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?
Marco Infante da Câmara DDS, MsC, PhD
m_infante2@hotmail.com
marco.camara@iucs.cespu.pt

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Prof Marco Infante da Câmara

ORCID ID
https://orcid.org/0000-0002-9551-5407

Contact details
Rua Correia de Sá n 107
Porto
Portugal
4150-229
+351914112775
m_infante2@hotmail.com

Type(s)
Public

Contact name
Dr Rosana Costa

ORCID ID
https://orcid.org/0000-0003-2462-4734

Contact details
Rua de Gondim n221 Vale São Cosme
Vila Nova de Famalicão
Portugal
4770-570
+351 914240555
rosana_gcosta@hotmail.com

Type(s)
Scientific

Contact name
Prof Marta Relvas

ORCID ID
https://orcid.org/0000-0003-0713-2041

Contact details
Rua Correia de Sá n 107
Porto
Portugal
4150-229
+351 914112775
marta.relvas@iucs.cespu.pt

Type(s)
Public, Scientific, Principal investigator

Contact name
Prof Marco Infante da Câmara

Contact details
Rua Correia de Sá n 107
Porto
Portugal
4150-229
+351914112775
marco.camara@iucs.cespu.pt

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
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

Study type(s)
Quality of life

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(s)
Pain perception measured using the Visual Analogue Scale during the first week after surgery

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
60 years

Sex
All

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
Gandra

Portugal
4585-116

Sponsor information

Organisation
SUAVEMED

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

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?
Results article		25/07/2024	25/07/2024	Yes	No
Participant information sheet			18/03/2024	No	Yes