

# 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.

<b>Submission date</b> 10/03/2024	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 18/03/2024	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 25/07/2024	<b>Condition category</b> Oral Health	<input type="checkbox"/> 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 chosen 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

## 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](mailto: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

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**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?
<a href="#">Results article</a>		25/07/2024	25/07/2024	Yes	No
<a href="#">Participant information sheet</a>			18/03/2024	No	Yes