

# Should bone grafts in the upper jaw be allowed to heal for 3 or 6 months before inserting dental implants?

|                                        |                                                   |                                                                                                   |
|----------------------------------------|---------------------------------------------------|---------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>14/10/2019   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>16/10/2019 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>22/10/2021       | <b>Condition category</b><br>Oral Health          | <input type="checkbox"/> Individual participant data                                              |

## Plain English summary of protocol

### Background and study aims:

Dental implants involve inserting a screw into the jaw. When the bone has healed around the jaw and the screw is tightly held, an artificial tooth (dental prosthesis) can be attached to the screw. Where there has been bone loss, substitute bone material can be added in a separate procedure so that there is enough bone to hold the screw and prosthesis firmly. This study is investigating whether the initial bone addition to the back of the upper jaw should be allowed to heal for 3 or 6 months before the implant screw is inserted.

### Who can participate?

Otherwise healthy adults who have lost teeth in the upper jaw but do not have enough bone to insert an implant screw.

### What does the study involve?

The participants will be randomly allocated to one of two groups. All participants receive the same treatment, which involves the initial bone addition procedure followed later by insertion of the implant screw. One group will wait 6 months between the bone addition and implant insertion, as is currently usual. The other group will wait 3 months.

### What are the possible benefits and risks of participating?

Participants will not pay for the materials used, the 6-month check-ups and oral hygiene treatments. Risks of participating are the same as for anyone undergoing this procedure, including injury or inflammation of the sinuses, infection, bleeding and implant failure.

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

July 2018 to December 2021

### Who is funding the study?

Semmelweis University Doctoral School of Clinical Medicine (Hungary)

Who is the main contact?

Dr. Bálint Trimmel, balint.trimmel@dent.semmelweis-univ.hu

## Contact information

### Type(s)

Public

### Contact name

Dr Bálint Trimmel

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## Additional identifiers

### Protocol serial number

Sinus-Allo-PRF-2018-01

## Study information

### Scientific Title

Maxillary sinus augmentation with A-RRF and serum albumin-coated allograft- prospective randomized trial for the determination of the optimal healing time for dental implant loading

### Study objectives

This randomized clinical study investigates the bone healing potential of advanced platelet rich fibrin (A-PRF) in combination with serum albumin-coated allograft (BoneAlbumin) after lateral sinus floor elevation.

The hypothesis of this study is that the use of A-PRF with BoneAlbumin will produce similar bone formation after 3 months of healing (test group) than the control group (6 months of healing). There will be no difference in implant stability quotient (ISQ) of the dental implants in the two treatment groups.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

1. Approved 18/09/2018, Office of the Chief Medical Officer of the National Public Health and Medical Service (2-6. Albert Flórián út, Budapest, H-1097 Hungary; tisztifoorvos@emmi.gov.hu; :

(+36 1) 476 1100), ref: 42292-5/2018/EKU

2. Approved 18/09/2018, Scientific and Research Ethics Committee of the Health Science Council (25 Alkotmány u., Budapest, H-1054, Hungary; : (+36 1) 795 1192; attilane.gombos@emmi.gov.hu), ref: 31068-7/2018/EÜIG

## **Primary study design**

Interventional

## **Study design**

Single-centre randomized controlled trial

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Bone allografting to support dental implants

## **Interventions**

The surgical procedure and the applied grafts for sinus augmentation from lateral approach are the same for both study arms. Grafting materials are advanced platelet rich fibrin (A-PRF) in combination with serum albumin-coated allograft (BoneAlbumin) in both treatment groups. The test and control group differ only in the graft healing period (3 vs 6 months) .

The surgical sites will randomly divide the participants into two groups by tossing a coin after the first surgical intervention is completed (sinus augmentation). Dental implants are placed 3 months (test) or 6 months (control) after bone augmentation. At the time of implant placement, bone core biopsy samples are collected directly from the implant sites with the use of a trephine bur for histological, histomorphometrical and micro-computerized tomography analysis. Histomorphometric and micro-computerized tomography analysis are performed by two investigators blinded to the treatment group. ISQ values are recorded by an Osstell device at the time of implant placement and at appointments 6, 8, 10, 12 weeks postoperatively. Prosthetic rehabilitation begins 3 months after implant placement. For follow-up, 6-month periods after final prosthesis delivery will be applied.

## **Intervention Type**

Procedure/Surgery

## **Primary outcome(s)**

Percentage of newly formed bone calculated from bone biopsy samples collected from the site of dental implant placement by micro-CT and histomorphometry at 3 months (test group) and 6 months (control group) after surgery

## **Key secondary outcome(s)**

1. Percentage of residual graft calculated from bone biopsies collected from the site of dental implant placement by micro-CT and histomorphometry at 3 months (test group) and 6 months (control group) after surgery
2. Percentage of connective tissue calculated from bone biopsies collected from the site of dental implant placement by micro-CT and histomorphometry at 3 months (test group) and 6 months (control group) after surgery
3. Implant stability quotient (ISQ) measured with Osstell ISQ device at implant placement and 6, 8, 10, 12 weeks after surgical intervention

**Completion date**

02/01/2020

## **Eligibility**

**Key inclusion criteria**

1. Systemically healthy patients aged over 18 years
2. Requiring implant prostheses and oral rehabilitation
3. Insufficient residual height in posterior maxilla requiring a sinus augmentation from lateral approach to insert the implants (residual crest height  $\leq 5$  mm)

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

All

**Total final enrolment**

30

**Key exclusion criteria**

1. Current pregnancy or intention to become pregnant during the study follow-up period
2. Sinusitis
3. Smoking
4. Alcoholism
5. Severe haematological disorder or disease
6. History of chronic hepatitis or liver cirrhosis
7. Diabetes mellitus with poor metabolic control
8. Receiving dialysis
9. Metabolic bone disease
10. Taking bisphosphonates drugs whether orally or intravenously
11. Undergoing or having received radiotherapy, chemotherapy or immunosuppressive therapy
12. Any other inability to participate in the study

**Date of first enrolment**

01/10/2018

**Date of final enrolment**

30/01/2020

# Locations

## Countries of recruitment

Hungary

## Study participating centre

**Semmelweis University,**

Szentkirályi utca 47.

Budapest

Hungary

1088

# Sponsor information

## Organisation

Semmelweis University Doctoral School of Clinical Medicine

## ROR

<https://ror.org/01g9ty582>

# Funder(s)

## Funder type

University/education

## Funder Name

Semmelweis Egyetem

## Alternative Name(s)

Semmelweis University

## Funding Body Type

Private sector organisation

## Funding Body Subtype

Universities (academic only)

## Location

Hungary

# Results and Publications

## Individual participant data (IPD) sharing plan

Current publication and dissemination plan and IPD sharing statement as of 05/02/2021:  
We intend to publish the following data in an open access peer-reviewed journal: participant data (age, gender), surgical site data (sinus widths, alveolar ridge height, sites of implant placement and bone core biopsy), data of histomorphometric analysis (percentage of newly formed bone, percentage of residual graft and percentage of nonmineralized tissue) and data of micromorphometric analysis (bone volume fraction, bone surface density, bone surface/volume ratio, trabecular thickness, trabecular separation, trabecular bone pattern factor, total porosity, open porosity, connectivity) based on bone core biopsy samples, data of resonance frequency analysis.

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Previous IPD sharing statement:

If a researcher needs any specific data (for example raw data of any analysis) for a review article or meta-analysis, these data will be available upon request from Dr. Bálint Trimmel (trimmel.balint@dent.semmelweis-univ.hu).

The study protocol, including the applied consent form, was reviewed and approved before patient enrollment by the Scientific and Research Ethics Committee of the Health Council of Hungary under registration number 31068-7/2018/EÜIG and by the Office of Chief Medical Officer of the National Public Health and Medical Service of Hungary under registration number 42292-5/2018/EKU.

The participants signed an informed consent form before enrollment, in which they agreed that the epidemiological information and measurement results obtained from the study could be used for scientific purposes.

After enrollment the participants were code masked for data anonymisation.

## IPD sharing plan summary

Available on request

## Study outputs

| Output type                     | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> |         | 06/04/2021   | 15/04/2021 | Yes            | No              |