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

Submission date	Recruitment status	[_] Prospectively registered
14/10/2019	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
16/10/2019	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
22/10/2021	Oral Health	

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

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Study design
Single-centre randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 trephin 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 measure
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

Secondary outcome measures
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

Overall study start date
27/07/2018

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 ≤5 mm)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30

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
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Sponsor information

Organisation
Semmelweis University Doctoral School of Clinical Medicine

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Sponsor type
University/education

Website
http://semmelweis.hu/phd/en/doktori-iskolak-en/klinikai-orvostudomanyok-en/

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

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
30/06/2021

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.

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?
Results article		06/04/2021	15/04/2021	Yes	No