

The effect of different gum graft materials in preventing bone resorption after tooth extraction: a clinical trial

Submission date 21/06/2023	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 05/07/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 20/02/2025	Condition category Oral Health	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

After dental (tooth) extraction, bone resorption/remodelling is expected as a result of the healing process. However, this could have a negative impact on the dental implants used to replace missing teeth when this remodelling is too extensive or the residual bone is too thin. Ridge preservation techniques are interventions aimed at minimising this amount of bone resorption and therefore increasing the probability of successful implant placement without the need for any artificial bone graft. The aim of this study is to compare two treatments to achieve more efficient bone preservation after dental extraction.

Who can participate?

Healthy adult patients aged 18 to 90 years who require dental extraction where implant therapy is a feasible option

What does the study involve?

Participants are randomly allocated to one of two groups. In the control group, a xenograft (Bio-oss) in combination with an autogenous gingival (gum) graft will be used as a soft tissue seal. In the intervention group, a xenograft (Bio-oss) is used with another xenograft material (Muograft) as a soft tissue seal.

What are the possible benefits and risks of participating?

The main benefit of ridge preservation procedures is to increase the amount of available bone for dental implant placement at a later stage whereas the risks of these procedures are minimal or similar to any other oral surgery.

Where is the study run from?

Murcia University Teaching Hospital (Morales Meseguer) (Spain)

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

January 2022 to January 2024

Who is funding the study?
Universidad de Murcia (Spain)

Who is the main contact?
Dr Guillermo Pardo Zamora, gparza@um.es

Contact information

Type(s)

Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

RUxFMqXf-Uhdslxv5-1DnV1zfn-BBJQx6TC

Study information

Scientific Title

The effect of free gingival graft and connective tissue substitutes on the preservation of the ridge after tooth extraction: a clinical trial

Study objectives

The aim of this study was to test the main null hypothesis that there were no differences in alveolar preservation using xenograft material and Mucograft as a soft tissue seal vs the use of the same xenograft material and autogenous soft tissue graft as a seal vs the alternative hypothesis of a difference at 6 months.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 05/01/2022, University of Murcia Ethics Committee (Universidad De Murcia Campus de la Merced. Calle Santo Cristo, Murcia, 30001, Spain; +34 (0)868 88 36 14; comision.etica.investigacion@um.es), ref: RUxFMqXf-Uhdslxv5-1DnV1zfn-BBJQx6TC

Study design

Randomized controlled clinical trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Alveolar ridge preservation after dental extraction

Interventions

Patients were randomly assigned to the test or control group by balanced block randomization using a computer-generated table. Treatment assignment was concealed to the treating surgeon by opaque envelopes that were opened only after the completion of tooth extraction.

In the control group, a xenograft (Bio-oss) in combination with an autogenous gingival graft will be used as a soft tissue seal. In the intervention group, a xenograft (Bio-oss) is used with another xenograft material (Muograft) as a soft tissue seal.

Intervention Type

Procedure/Surgery

Primary outcome(s)

Soft tissue volumetric changes measured in plaster study models obtained at baseline, 3 and 6 months. Additionally, further measurements will be taken with a periodontal probe at baseline and 6 months to evaluate the location of certain anatomic landmarks using a custom-made prefabricated stent for each patient.

Key secondary outcome(s)

1. Hard tissue volumetric changes assessed with intraoperative measures at the bone level at the time of dental extraction and at 6 months before placement of dental implants at those locations. A periodontal probe and calipers will be used to evaluate the location of certain anatomic landmarks using a custom-made prefabricated stent for each patient.
2. Probing pocket depth measured with a periodontal probe at baseline and 6 months
3. Gingival phenotype measured with a periodontal probe at baseline and 6 months
4. Plaque and gingival bleeding indexes measured with a periodontal probe at baseline and 6 months

Completion date

01/01/2024

Eligibility

Key inclusion criteria

Healthy adult patients for which dental extraction was required and implant therapy was a feasible option to be offered/discussed

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

90 years

Sex

All

Total final enrolment

30

Key exclusion criteria

1. Patients with medical history in which any dental intervention would be contraindicated such as uncontrolled diabetes, head and neck radiation for cancer treatment or current treatment with intravenous bisphosphonates
2. Presence of clinically symptomatic periapical radiolucencies, acute abscesses or chronic sinus tracts at the site of extraction
3. Heavy smokers (+10 cigarettes/day)
4. Pregnancy
5. Presence of active periodontal disease
6. Inability or unwillingness to return for follow-up visits

Date of first enrolment

10/01/2022

Date of final enrolment

01/03/2023

Locations

Countries of recruitment

Spain

Study participating centre

Hospital Universitario Morales Meseguer

Avenida Marques de los Velez

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Murcia

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Sponsor information

Organisation

Hospital General Universitario Morales Meseguer

ROR

<https://ror.org/00cfm3y81>

Funder(s)

Funder type

University/education

Funder Name

Universidad de Murcia

Alternative Name(s)

University of Murcia

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

Spain

Results and Publications

Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are currently unknown and will be made available at a later stage.

IPD sharing plan summary

Data sharing statement to be made available at a later date