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A study on wound healing using a novel bone graft after third molar removal surgery

Submission date 08/05/2026	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 15/05/2026	**Overall study status** Ongoing	
Last Edited 11/05/2026	**Condition category** Oral Health	

Plain English summary of protocol

Background and study aims
Lower wisdom teeth are usually impacted due to insufficient space, the presence of obstruction or abnormal position in the jaw. This often leads to inflammation or infection of the gums surrounding the wisdom teeth and decay of the adjacent second molar. Hence, surgical removal is commonly performed on impacted lower wisdom teeth. This procedure often results in loss of bone and soft tissue at the socket of the lower wisdom tooth, causing gum problems to the adjacent second molar, which can be prevented by packing bone graft into the socket of the wisdom tooth and placing a membrane over it to stimulate bone formation and soft tissue regeneration. However, there is no study done on this carbonate apatite bone graft and Cytrans membrane for the healing of the adjacent second molar after wisdom tooth removal. This study aims to investigate and compare the effects on wound healing by application of a synthetic bone graft material (Cytrans) and platelet-rich fibrin (PRF) with resorbable membrane (Cytrans Elashield) in the sockets after removal of the lower wisdom tooth.

Who can participate?
Patients aged 18 to 35 years old who are medically fit and who require surgical removal of bilateral impacted sound lower third molars.

What does the study involve?
Before the surgery, X-rays of the lower wisdom teeth on both sides will be taken for assessment. Measurements will also be taken from the gums as a baseline for comparison.
Study participants will undergo surgery for the removal of lower wisdom teeth on both sides at the same visit, either under local anaesthesia or general anaesthesia. One socket of the wisdom teeth will be cleaned and packed with bone graft, another socket will be packed with PRF, followed by placement of PLACL (Cytrans Elashield) membrane on both sides. A stitch will be placed across the socket to secure the bone graft and membrane.
Participants will be given antibiotics and two types of painkillers after the surgery for one week. They will also receive a set of post-surgery care instructions. Participants are required to come to the clinic for follow up for a total of 4 times, which are at 1 week, 1 month, 3 months and 6 months after the surgery. Measurements on the gums will be done during all 4 follow-up visits. X-rays will be taken during the final follow-up at 6 months after surgery. Each session will take approximately 30 minutes.

What are the possible benefits and risks of participating?
What will be the benefits of the study?
(a) To the participant?
Each participant contributes to the study of both Cytrans bone graft and Cytrans Elashield membrane for bone healing and soft tissue regeneration at the socket of the wisdom teeth. This provides a significant impact on the future management for patients undergoing wisdom tooth surgery with reduced complications at the adjacent second molar. This would be impossible without their participation in the study.
(b) To the investigator?
The future benefit to be gained from this research is the consideration of choices of bone graft and membrane to be placed over the grafted socket to enhance bone formation and soft tissue regeneration, restoring the health of the adjacent second molar. This can be applied to the extraction sockets of other teeth for the same reason before teeth replacement with a prosthesis.

What are the possible risks/complications/adverse effects that may happen?
Although the materials used in this study are medically safe, allergies remain possible. The participant may experience pain, redness, and swelling of the gums after the surgery. The stitches may loosen, and the materials placed may dislodge from the socket before the first follow-up visit. Infection may also occur after the surgery. Failure of the graft is possible; if this occurs, the graft will be removed and followed by alternative management.
There is also a possible risk of uncontrolled bleeding and injury to the nerve below the wisdom teeth during the surgery. Should a nerve injury occur, the participant may experience numbness of the lower lip and chin, which may be temporary or permanent. Although the likelihood of this is low, the participant should be aware of this possibility.
In the event of adverse effects, the participant is required to report to the researcher(s) using the contact number(s) provided. The participant is advised to seek immediate medical care at Universiti Malaya Medical Centre (UMMC) or at the nearest available medical facility should any adverse events arise.

Can I refuse to take part in the study?
Participation is totally voluntary. Participants do not have to explain why they prefer not to take part in the study, and it will not affect their dental treatment. Participant data obtained from this study will be anonymized and kept confidential.

Where is the study run from?
Department of Oral and Maxillofacial Clinical Sciences, Faculty of Dentistry, Universiti Malaya.

When is the study starting and how long is it expected to run for?
February 2026 to May 2027

Who is funding the study?
Universiti Malaya research grants.

Who is the main contact?
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Study information

Scientific Title
A comparative study on the bone formation and soft tissue healing at distal surface of mandibular second molar following removal of the mandibular third molar using carbonate apatite bone graft

Study objectives
1. To evaluate the wound healing (periodontal pocket depth, clinical attachment loss, radiographic bone level) on lower second molars post surgical removal of lower third molars using carbonate apatite alloplastic bone graft with resorbable membrane without primary closure
2. To compare the effects of carbonate apatite bone graft and platelet rich fibrin (PRF) with resorbable membrane without primary closure on wound healing (periodontal pocket depth, clinical attachment loss, radiographic bone level), adjacent second molar periodontal health and keratinised tissue regeneration post-surgical removal of lower third molars

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 13/01/2026, Medical Ethics Committee, Faculty of Dentistry (Faculty of Dentistry, University of Malaya, Kuala Lumpur, 50603, Malaysia; +60 03-79674862; chaiwl@um.edu.my), ref: DF OS2601/0006 (P)

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Soft tissue defect and bone defect (Periodontal defect) on distal surface of lower second molars due to presence of lower third molars

Interventions
This study has a split-mouth double-blind design, in which all participants will undergo the same treatment (left and right lower third molar removal), but the intervention site (platelet-rich fibrin (PRF) versus carbonate apatite bone graft) will be randomised. The randomisation is generated by the research randomiser, https://www.randomizer.org/.

After surgical removal of both left and right lower third molars, one side of the extraction socket will be grafted with carbonate apatite alloplastic bone graft, while the other side will have PRF placed. Both sites will be covered with a resorbable membrane, and two holding sutures will be placed.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Periodontal pocket depth measured using a periodontal probe to assess pocket depth on distobuccal, mid-distal and distolingual aspects of lower second molars at baseline before surgical removal of lower third molars, 3 and 6 months after the surgery

2. Clinical attachment loss measured using a periodontal probe to assess the distance from the cemento-enamel junction (CEJ) to the base of periodontal pocket on distobuccal, mid-distal and distolingual aspects of lower second molars at baseline before surgical removal of lower third molars, 3 and 6 months after the surgery

3. Radiographic bone level measured using radiographs to assess the distance between the cemento-enamel junction (CEJ) to the level of the bone distal to lower second molars at baseline before surgical removal of lower third molars, and 6 months after the surgery

Key secondary outcome(s)
1. Healing index measured using Landry Healing Index Criteria (1988) at baseline before the surgical removal of lower third molars, 3 and 6 months after the surgery

2. Width of keratinised gingiva measured using a periodontal probe to assess the bucco-lingual width of gingiva 6mm distal to lower second molars at baseline before the surgical removal of lower third molars, 3 and 6 months after the surgery

Completion date
31/12/2026

Eligibility

Key inclusion criteria
1. Patient who requires surgical removal of bilateral impacted sound lower third molars
2. Impacted bilateral third molars as Class I or II with Level A or B according to Pell and Gregory's classification
3. Presence of disease free lower second molars adjacent to lower third molars planned for extraction
4. Patient aged 18-35 years old who are medically fit

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
35 Years

Sex
All

Total final enrolment
0

Key exclusion criteria

1. Impacted lower third molars associated with fracture of angle of mandible, radiological evidence of cyst or tumour, incomplete root formation, acute pulpitis or severe pericoronitis that is not under control or gross dental caries with ICDAS 05/06
2. Retained roots of lower third molar with history of removal or coronectomy of unerupted or impacted lower third molar
3. Patients with periodontitis, active smoker
4. Patients with absence of lower second molars
5. Medically compromised patients
6. Pregnant women
7. Patient on oral contraceptives or long term steroids
8. Current or previous bisphosphonate therapy or history of radiotherapy to the jaws

Date of first enrolment
09/02/2026

Date of final enrolment
30/06/2026

Locations

Countries of recruitment
Malaysia

Sponsor information

Organisation
University of Malaya

ROR
https://ror.org/00rzspn62

Funder(s)

Funder type

Funder Name
Universiti Malaya

Alternative Name(s)
University of Malaya, University Malaya, Malayan University, King Edward VII College of Medicine, Raffles College, University of Malaya in Singapore, , , , UM

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Malaysia

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 5	31/12/2023	14/05/2026	No	Yes