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Comparative evaluation of bone grafting using rhBMP-2 versus autogenous bone graft in patients with cleft lip and palate

Submission date 26/05/2025	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 27/05/2025	**Overall study status** Completed	
Last Edited 27/05/2025	**Condition category** Oral Health	

Plain English summary of protocol

Background and study aims
Secondary alveolar bone grafting is an important surgical procedure used to repair the alveolar cleft in patients with cleft lip and palate. This procedure helps to restore the bone in the affected area, improving dental stability and facial structure. The study aims to compare the effectiveness of using human bone morphogenetic protein-2 (BMP-2) versus traditional autogenous bone grafts for secondary alveolar bone grafting, focusing on bone volume formation, healing outcomes, and patient satisfaction.

Who can participate?
Children aged 8 to 11 years with complete unilateral alveolar cleft type (A), class III, who are classified as ASA I or II and have good oral hygiene. Participation requires written informed consent from the legal guardian.

What does the study involve?
Eligible participants will undergo secondary alveolar bone grafting. Patients will be randomly assigned to receive either BMP-2 treatment or an autogenous bone graft. The volume of newly formed bone will be measured using multi-slice computed tomography (MSCT) before surgery and six months after. Healing, complications, and patient satisfaction will be monitored at regular intervals up to six months post-surgery.

What are the possible benefits and risks of participating?
Participants may benefit from improved bone formation and facial function. Risks include potential surgical complications and mild postoperative discomfort. All procedures will be performed under general anesthesia by experienced surgeons, and patients will be closely monitored during recovery.

Where is the study run from?
National Hospital and Children’s Hospital, Mazzeh Highway, Damascus, Syria.

When is the study starting and how long is it expected to run for?
January 2023 to January 2025

Who is funding the study?
Damascus University, Syria.

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
A randomized clinical trial to evaluate secondary alveolar bone grafting using recombinant human bone morphogenetic protein-2 (rhBMP-2) versus autogenous bone in patients with unilateral cleft lip and palate

Study objectives
We hypothesize that secondary alveolar bone grafting using rhBMP-2 provides comparable or superior clinical and radiographic outcomes compared to autogenous bone grafts in patients with unilateral cleft lip and palate.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 01/02/2023, Biomedical Research Ethical Committee of Damascus University (Al-mazeh, Damascus, -, Syria; +963 (0)113341864; manager@hcsr.gov.sy), ref: 22749

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life, Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Cleft lip and palate

Interventions
Informed consent will be obtained from all participants prior to enrollment. Eligible patients with unilateral cleft lip and palate will be clinically and radiographically assessed to ensure they meet the inclusion criteria. Each participant will be randomly assigned to one of two treatment groups using a computer-generated randomization sequence.

On the day of surgery, all procedures will be performed under general anesthesia following standard preoperative protocols. In the autogenous graft group, alveolar bone grafting will be performed using particulate cancellous bone harvested from the anterior iliac crest. In the rhBMP-2 group, bone grafting will be performed using an absorbable collagen sponge (ACS) impregnated with recombinant human bone morphogenetic protein-2 (rhBMP-2), placed within the alveolar cleft defect.

All surgical procedures will be performed by the same surgical team to ensure standardization. Postoperative care, including antibiotics, analgesics, and oral hygiene instructions, will be standardized across both groups.

Intervention Type
Procedure/Surgery

Primary outcome measure

The volume of newly formed bone within the alveolar cleft, assessed using multislice computed tomography (MSCT). Preoperative cleft volume will be calculated from the initial MSCT scans. Six months postoperatively, the residual defect volume will be measured using the same imaging modality. The volume of newly formed bone will be determined by subtracting the postoperative residual cleft volume from the preoperative cleft volume. This volumetric analysis will be performed using specialized radiographic software to ensure precise measurement and consistency.

Secondary outcome measures

1. Radiographic Bone Density Assessment
Radiographic bone density of the newly formed bone will be measured six months postoperatively using multislice computed tomography (MSCT). Measurements will be limited to the internal portion of the grafted defect, excluding adjacent cortical bone. Hounsfield Units (HU) will be used as the measurement scale. Five consecutive 1-mm-thick axial slices will be analyzed, and the mean of these five slices will represent the final bone density value.
2. Fistula Presence Evaluation
The presence or absence of postoperative oronasal fistula will be assessed clinically and through patient inquiry at 10 days, 1 month, and 6 months after surgery.
3. Bone Graft Healing Complications
Complications related to bone graft healing will be evaluated using the Sanz-Martin criteria one month postoperatively. Parameters include wound dehiscence and presence or absence of infection.
4. Soft Tissue Healing
Early soft tissue healing will be assessed weekly during the first postoperative month using the Early Healing Index (EHI).
5. Postoperative Edema
Postoperative facial edema will be evaluated using the Chaudhary edema scoring system on days 3, 5, and 7 following surgery.
6.Hospital Stay Duration
The number of days each patient remains hospitalized postoperatively will be recorded for both groups.
7. Patient Satisfaction with the Surgical Procedure
One month postoperatively, patient satisfaction regarding the surgical procedure itself will be assessed using a visual analog scale (VAS) ranging from 0 to 100.
8. Patient Satisfaction with the Outcome
Six months postoperatively, patient satisfaction with the treatment outcome will be evaluated using a visual analog scale (VAS) ranging from 0 to 100.
9. Periodontal Assessment of Adjacent Teeth
9.1. Probing Depth: Measured at six sites around each tooth adjacent to the alveolar cleft using a UNC-15 periodontal probe, preoperatively and at 3 months postoperatively.
9.2. Bleeding on Probing: Recorded as positive (+) or negative (–) within 15–20 seconds after probing at the same six sites, both before surgery and three months after.
9.3. Width of Keratinized Tissue: Measured at the mid-buccal surface from the gingival margin to the mucogingival junction using the periodontal probe, both before surgery and at 3 months postoperatively.

Overall study start date

05/01/2023

Completion date

05/01/2025

Eligibility

Key inclusion criteria
1. Patients with complete unilateral alveolar clefts of type (A), class III according to the LAHS classification, requiring secondary alveolar bone grafting. This type represents an alveolar cleft extending to the nasal floor.
2. Age between 8 and 11 years.
3. Classified as ASA physical status I or II.
4. Good oral hygiene, defined as a plaque index not exceeding 40% based on O'Leary's index.
5. Written informed consent obtained from the patient's legal guardian after full explanation of the study purpose and procedures.

Participant type(s)
Healthy volunteer

Age group
Child

Lower age limit
8 Years

Upper age limit
11 Years

Sex
Both

Target number of participants
14

Key exclusion criteria
1. Presence of bilateral clefts, or cleft lip without involvement of the palate.
2. Presence of additional craniofacial abnormalities or congenital syndromes.
3. Patients with systemic conditions that contraindicate general anesthesia or may impair wound and bone healing (ASA class III or IV).
4. History of previous infection at the alveolar cleft site.
5. Patients who have undergone prior secondary alveolar bone grafting.
6. Refusal of participation by the child or legal guardian.

Date of first enrolment
01/06/2023

Date of final enrolment
01/09/2024

Locations

Countries of recruitment
Syria

Study participating centre
National Hospital and Children's Hospital
Mazzeh Highway
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Sponsor information

Organisation
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ROR
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Funder(s)

Funder type
University/education

Funder Name
Damascus University

Alternative Name(s)
University of Damascus, , DU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Syria

Results and Publications

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

Intention to publish date
01/06/2025

Individual participant data (IPD) sharing plan
The data to be shared will include summarized statistical results derived from individual participant data.
These data will be made accessible following the publication of the study findings.
Informed consent for data sharing will be obtained from all participants or their legal guardians.
All shared data will be completely anonymized to ensure participant confidentiality.
There are no ethical or legal barriers restricting the sharing of these data

IPD sharing plan summary
Available on request