

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Investigation of the effect of corticocancellous iliac graft on maxillary canine eruption

Protocol summary

Study aim

Determination of the percentage of canine eruption after corticocancellous iliac graft

Design

Non randomized split mouth clinical trial of 41 patients with congenital palatal cleft

Settings and conduct

In this study, the reconstruction of the alveolar gap in the congenital cleft palate patients referred to Mashhad dental school is done. corticocancellous iliac graft in wedge shape is used to reconstruct the alveolar cleft. The other side of maxilla who has no gap is considered as control group. Clinical and radiographic examinations are performed before and after 14 days, 3 and 12 months after surgery at Mashhad dental school. The canine angle is measured as an angle between the longitudinal axis of the crown tip to the tip of the root and the plan drawn from two condyles in the panoramic radiograph. The amount of bone formed is evaluated in PA radiography by Bergland method.

Participants/Inclusion and exclusion criteria

Inclusion criteria: The full one-sided cleft lip and palate without any other craniofacial anomalies orthopedic jaw expansion was performed for children, and there is space for canine tooth eruption. At the age of second mixed dentition with unerupted canine tooth bud with root formation rate of 1/3 to 2/3. exclusion criteria: Infection and dehiscence of graft recipient's site and patients who do not come for follow up.

Intervention groups

Children with congenital alveolar clefts.

Main outcome variables

Eruption height of canine teeth; bone volume that formed in the cleft area

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190126042491N1**

Registration date: **2020-07-11, 1399/04/21**

Registration timing: **registered_while_recruiting**

Last update: **2020-07-11, 1399/04/21**

Update count: **0**

Registration date

2020-07-11, 1399/04/21

Registrant information

Name

Amin Rahpeyma

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-23, 1398/02/03

Expected recruitment end date

2020-08-24, 1399/06/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the effect of corticocancellous iliac graft on maxillary canine eruption

Public title

Investigation of the effect of pelvic graft for cleft palate on canine tooth eruption

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The complete one-sided cleft lip and palate without any other craniofacial anomalies. Children have orthopedic expansion before surgery, and there is space for canine tooth eruption In children with secondary mixed dentition that have unerupted canine bud with root formation rate of 1:3 to 2:3

Exclusion criteria:

Infection dehiscence Patients Do not refer for follow-up

Age

From **8 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **41**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Vakilabad Blvd, Ferdowsy University, Dental college

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948959

Approval date

2019-03-10, 1397/12/19

Ethics committee reference number

IR.MUMS.DENTISTRY.REC.1397.116

Health conditions studied

1

Description of health condition studied

Alveolar cleft of maxilla

ICD-10 code

K08.8

ICD-10 code description

Other specified disorders of teeth and supporting structures

Primary outcomes

1

Description

Canine eruption

Timepoint

3 and 12 months after graft surgery

Method of measurement

Panoramic Radiography, expose in mouth

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Alveolar cleft side of 41 patients undergoing corticocancellous anterior iliac crest graft surgery with the wedge method.

Category

Treatment - Surgery

2

Description

Control group: Non-cleft side of 41 patients that no extra work is done.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem hospital of Mashhad University of medical science

Full name of responsible person

Dr Amin Rahpeyma

Street address

department of oral and maxillofacial surgery , Dental school, Mashhad , Iran

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Sponsors / Funding sources

1

Sponsor

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Adel Sharifi Rayeni
Position
Resident of Oral and Maxillofacial surgery
Latest degree
Medical doctor

Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

After completing the study, the paper is sent for publication in scientific journals.

When the data will become available and for how long

About two months after the completion of the study, the paper is sent for publication and will be available in the journal.

To whom data/document is available

For those who have access to scientific journals, they will be available.

Under which criteria data/document could be used

It will be available to anyone interested.

From where data/document is obtainable

From the journal where the article will be printed will be accessible.

What processes are involved for a request to access data/document

Interested persons can receive study information through email after publishing the article.

Comments