

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

The success evaluation of bone grafts treatment in patients with unilateral alveolar cleft using mixture of allograft and symphysis bone compared to iliac bone graft alone

Protocol summary

Study aim

Determining and Comparing the Average Percentage of Bone Formed in the Alveolar Fissure in Different Ways

Design

Clinical Trial with Control Group, with Parallel Groups, Double-Blind, Randomized. Patients list randomized by computer program.

Settings and conduct

Iliac crest bone graft use commonly as donor site in alveolar cleft patients operation. In this study, we will compare iliac bone graft versus chin symphysis bone combine with allograft in operations results success. This clinical study will perform in Alzahra Hospital, Isfahan. Patients with unilateral alveolar cleft were randomly divided into two groups: Group A: Patients who will be treated with combination of chin symphysis and allograft Group B: Patients who will be treated with iliac bone graft alone. Before and one year after treatment CBCT will be used to measure the volume of new bone regeneration. Patients not know the location of donor site before the operation, but they will fulfilled informed consent for both methods. The practitioner evaluating the CBCT results not know in which group the patients are.

Participants/Inclusion and exclusion criteria

Entry Requirements: 1) Patients with Unilateral Alveolar Defects 2) Patients in Mixed Dentition Exit conditions: 1) Bilateral Alveolar Cleft 2) Presence of Systemic Diseases 3) Presence of Pathologic Disorders 4) History of Chemotherapy or Radiotherapy 5) History of Previous Failed Alveolar Graft.

Intervention groups

1) The intervention group includes patients with Unilateral Alveolar cleft who receive Chin Symphysis Bone Combination with Bone Allograft 2) The comparison group includes patients with Unilateral Alveolar cleft who receive anterior iliac bone graft alone.

Main outcome variables

evaluation of Donor Site' evaluation of Complications Related to the Donor Site' Costs evaluation Compared to other Bone Regeneration Methods' evaluation the Duration of Surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210515051308N1**
Registration date: **2021-06-25, 1400/04/04**
Registration timing: **retrospective**

Last update: **2021-06-25, 1400/04/04**

Update count: **0**

Registration date

2021-06-25, 1400/04/04

Registrant information

Name

Davood Davari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3234 9543

Email address

davari-d@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-03-21, 1396/01/01

Expected recruitment end date

2017-09-23, 1396/07/01

Actual recruitment start date

2017-03-21, 1396/01/01

Actual recruitment end date

2017-12-22, 1396/10/01

Trial completion date

2018-12-22, 1397/10/01

Scientific title

The success evaluation of bone grafts treatment in patients with unilateral alveolar cleft using mixture of allograft and symphysis bone compared to iliac bone graft alone

Public title

Evaluation of Alveolar Cleft Repair With Two Bone Grafting Methods

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with Unilateral Alveolar Cleft Patients with Mixed Dentition Informed Consent for Studing Treatment Methods

Exclusion criteria:

Bilateral alveolar cleft History of previous surgery in the area History of radiotherapy in the area Existence of systemic disease

AgeFrom **8 years** old to **14 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample sizeTarget sample size: **22**Actual sample size reached: **22****Randomization (investigator's opinion)**

Randomized

Randomization description

Patients are selected by available sampling. Simple randomization based on a table of random numbers will be done . according to this participants will dividing into intervention and control groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

1)The Advantages and Disadvantages of Both Treatments Were Explained to Patients Who Entered the Study. Patients Entered the Treatment Phase with Informed Consent but Were Not Alert Which Method Will be Used in the Operation Room. 2)The Radiologists, Who Examined the Dimensions of the Alveolar Cleft and Repair Using CBCT, Did Not Alert Which Surgical Procedure Would be Used for the Patient.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Isfahan University of Medical Sciences

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Koorosh Blding., Sajad Ave., Atash(Meghdad) St., Khayam Highway

City

esfahan

Province

Isfahan

Postal code

8184973641

Approval date

2021-05-20, 1400/02/30

Ethics committee reference number

397131

Health conditions studied**1****Description of health condition studied**

unilateral alveolar cleft

ICD-10 code

Q37.1

ICD-10 code description

Cleft hard palate with unilateral cleft lip

Primary outcomes**1****Description**

Percentage of Bone Formed in the Alveolar Cleft

Timepoint

Cleft Volume Measurement before Intervention and One Year after Surgery

Method of measurement

Cone-Beam Computed Tomography

Secondary outcomes**1****Description**

Determining of Treatment Complications

Timepoint

1 Week, 1 Month, 3 Month, 6 Month, 1 Year after Intervention

Method of measurement

Intervention groups

1

Description

Intervention group: Cortical bone fragments were extracted from the chin symphysis. For this purpose, sulcular incision of canine to canine was made in the mandible, 3 to 5 pieces of monocortical bone were extracted by a 6 mm trephine bur (Meisinger, Dusseldorf, Germany). The soft tissue incision was then sutured. A piece of the chin symphysis cortical bone was placed under the nasal mucosa. The other pieces were divided into smaller sizes and mixed with 2 to 5 mm allografts (Cenobone, Kish, Iran, two thirds autograft, one third allograft). The mixture filled the entire cleft area.

Category

Treatment - Surgery

2

Description

Control group: In these patients, a standard incision was used to access the anterior iliac crest. Based on the approximate size of the alveolar defect, a corticocancellous bone fragment was removed from the medial cortex of the anterior iliac crest by osteotome and mallet. The donor area (iliac) was sutured in three layers after washing. The extracted bone fragment was divided into smaller pieces and packed inside the alveolar defect so that a cortical wall was placed under the nasal mucosa.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Davood Davari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Bijan Movahedian Attar

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Department of Oral and Maxillofacial Surgery, Isfahan
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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Davood Davari

Position

Post graduate student of oral and maxillofacial
surgery

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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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

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

personal data of participants and results of the study except patients name and family can be shared

When the data will become available and for how long

Access will start after the article is published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

in order to perform similar research, various analyzes can be done

From where data/document is obtainable

Dr. Davood Davari davooddavari2011@yahoo.com.

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

After sending the email, the documents will be sent within a week.

Comments