Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The success evaluation of bone grafts treatment in patients with unilateral alveolar cleft using mixture of allograft and symphisis 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 symphisis 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 illic 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)

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+98 31 3234 9543

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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 symphisis 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
Age
From **8 years** old to **14 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target 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
Street address
Koorosh Bilding., Sajad Ave., Atash(Meghdad) St., Khayam Highway
City
esfahan
Province
Isfehan
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

Clinical Inspection

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

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esfahan

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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

Street address
Department of Oral and Maxillofacial Surgery, Isfahan University of Medical Sciences, Hezar Jerib St., Isfahan, Iran.

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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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Person responsible for updating data

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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