Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Investigating the effect of using hydroxyapatite mesh on the occurrence of fistula in patients undergoing primary palatoplasty by the Sommerlad intravelar veloplasty method

Protocol summary

Study aim
Investigating the effect of using hydroxyapatite mesh on the occurrence of fistula in patients undergoing primary palatoplasty by the Sommerlad intravelar veloplasty method referred to the Cleft Lip and Palate Center of Isfahan University of Medical Sciences in 2023 - 2024

Design
Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 2 on 64 patients. Random blocked method and table of random numbers will be used for randomization.

Settings and conduct
The current study is a double-blind clinical trial type study that will be conducted on patients undergoing primary palatoplasty using the intravelar veloplasty method referred to the cleft lip and palate center of Isfahan University of Medical Sciences in the time frame of 1402 to 1403.

Participants/Inclusion and exclusion criteria
Individuals with written informed consent from the patient's guardian or legal guardian to participate in the study, definite diagnosis of cleft palate, age under 3 years, surgery performed by a single surgeon and primary palatoplasty surgery by intravelar veloplasty method and using a microscope will enter the study. If the patient's legal guardian does not want to continue participating in the study, the patient will not be included in the study. If the follow-up time of 3 and 6 months is not completed, there are infections at the operation site, or the patient's condition worsens after the surgery, which requires other therapeutic interventions, and the start of new therapeutic interventions for patients that distorts the effect of the current intervention, the patient will be excluded from the study.

Intervention groups
The group with hydroxyapatite mesh will be the intervention group and the group without hydroxyapatite mesh will be the control group.

Main outcome variables
Occurrence of fistula

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240128060826N1**
Registration date: **2024-02-13, 1402/11/24**
Registration timing: **prospective**

Last update: **2024-02-13, 1402/11/24**
Update count: **0**

Registration date
2024-02-13, 1402/11/24

Registrant information

Name
Hossein Abdali

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 3620 2020

Email address
abdali@med.mui.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-02-20, 1402/12/01

Expected recruitment end date
2024-07-21, 1403/04/31

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of using hydroxyapatite mesh on the occurrence of fistula in patients undergoing primary palatoplasty by the Sommerlad intravelar veloplasty method

Public title
Investigating the effect of using hydroxyapatite mesh on the occurrence of fistula in patients undergoing primary palatoplasty by the Sommerlad intravelar veloplasty method
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Written informed consent from the patient's legal guardian to participate in the study Definitive diagnosis of cleft palate Surgery performed by a common surgeon Performing primary palatoplasty surgery using the intravelar veloplasty method and using a microscope
Exclusion criteria:
Presence of surgical site infections Unwillingness of the patient's guardian
Age
To **3 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **64**
Randomization (investigator's opinion)
Randomized
Randomization description
This stage will be Randomized Block Design. At this stage, patients will be divided into 2 blocks (32 blocks of 2). Then they are sorted according to the national code (the larger national code of the first row of the block and the smaller national code of the second row of the block). After that, we refer to the table of random numbers for each block. If the selected number was from 0 to 4, the patient in the first row will join group A and the patient in the second row will join group B. If the selected number was from 5 to 9, the patient in the first row will join group B and the patient in the second row will join group A. A blinded colleague determines that each of groups A and B will be the intervention group and the control group.
Blinding (investigator's opinion)
Double blinded
Blinding description
The patient and the person analyzing the data are not aware of the type of surgery, and the sealed envelope containing the selection of group A and B as stated in the randomization section is presented to the surgeon in the operating room.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of School of Medicine - Isfahan University of Medical Sciences
Street address
Vice Chancellor for Research and Technology, Building No. 4, Hezar Jerib St., Isfahan University of Medical Sciences and Health Services
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2024-01-13, 1402/10/23
Ethics committee reference number
IR.MUI.MED.REC.1402.387

Health conditions studied

1

Description of health condition studied
Cleft palate
ICD-10 code
Q35
ICD-10 code description
Cleft palate

Primary outcomes

1

Description
Occurrence of fistula
Timepoint
3 and 6 months after surgery
Method of measurement
Physical examination

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the patients of the intervention group, in addition to the routine care and surgical procedures that will be performed, a hydroxyapatite mesh (manufactured by Hamsan Baft Adelie, Iran) will be placed in the palate.
Category
Treatment - Surgery

2

Description
Control group: In the patients of the control group, routine care and Sommerled surgical procedure will be performed, without using hydroxyapatite mesh.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra Hospital
Full name of responsible person
Hossein Abdali
Street address
Alzahra Hospital, Sofeh Blvd.
City
Isfahan
Province
Isfehan
Postal code
8174675731
Phone
+98 31 3620 2020
Email
alzahra@mui.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Mansour Siavash
Street address
Building No. 4, Vice Chancellor for Research and Technology, Hezar Jerib St., Isfahan University of Medical Sciences and Health Services
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Postal code
8174673461
Phone
+98 31 3668 8138
Email
research@mui.ac.ir
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
Hossein Abdali
Position
Associate Professor
Latest degree
Subspecialist
Other areas of specialty/work
Plastic surgery
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Information is kept confidential.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not 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

Not applicable

Title and more details about the data/document

Information about the main outcome can be shared.

When the data will become available and for how long

After publishing the results

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Using data to complete studies

From where data/document is obtainable

Dr. Hossein Abdali, Isfahan University of Medical Sciences

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

By examining the researcher's request and providing sufficient documentation of his research and the reason for using the data can be provided.

Comments