

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

Applicability of Fibrin Glue in closure of nasal mucosa in bone grafting of alveolar clefts

Protocol summary

Summary

The aim of the present study is to evaluate the applicability of the fibrin glue in the closure of the nasal mucosa in alveolar cleft patients. This clinical trial would be conducted on patients of 9 years old and more referring to Al-Zahra Hospital during spring and summer of the present year (2011). A total of 15 consecutive patients who meet the inclusion criteria and sign the informed consent sheets would be placed in the intervention or control groups. Standard protocol of surgical bone grafting would be performed in the control group. Similar steps will be done for the patients in the intervention group except for the closure of the nasal mucosa which is accomplished with the aid of fibrin glue instead of standard suturing. The operating time, incidence of postoperative complications such as infection and wound dehiscence, alveolar height at the grafted site will be measured in each group and results will be compared in the two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201103055972N1**
Registration date: **2011-06-30, 1390/04/09**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-06-30, 1390/04/09

Registrant information

Name

Bijan Movahedian

Name of organization / entity

Isfahan university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 1792 2854

Email address

b_movahedian@dnt.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2011-04-01, 1390/01/12

Expected recruitment end date

2011-11-01, 1390/08/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Applicability of Fibrin Glue in closure of nasal mucosa in bone grafting of alveolar clefts

Public title

Applicability of Fibrin Glue in closure of nasal mucosa in bone grafting of alveolar clefts

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age of 9 years old and more, no systemic disease, no previous surgical treatment of the same problem, unilateral alveolar cleft, complete mental health Exclusion criteria: less than 9 years old, any previous bone grafting in the cleft area, any systemic disease, bilateral alveolar cleft, any mental or cognitive disease

Age

From **9 years** old

Gender

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **15****Randomization (investigator's opinion)**

Randomized

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 Isfahan University Of Medical sciences

Street address

Hezar Jarib Avenue

City

Isfahan

Postal code**Approval date**

2010-09-23, 1389/07/01

Ethics committee reference number

188127

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

Alveolar cleft

ICD-10 code

Q35.1, Q37

ICD-10 code description

Cleft hard palate, Unspecified cleft palate with bilateral cleft lip, Unspecified cleft palate with unilateral cleft lip

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

Bone healing in graft area

Timepoint

1 and 3 months after operation

Method of measurement

radiographic and clinical examination

2**Description**

duration of the procedure

Timepoint

At the end of the surgery

Method of measurement

timer (minute)

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

incidence of post operative infection

Timepoint

during the 3-months healing time period

Method of measurement

clinical observation

2**Description**

incidence of postoperative wound dehiscence

Timepoint

during the 3-months period of healing phase

Method of measurement

clinical observation

Intervention groups**1****Description**

Intervention group: standard surgical treatment with an exception of closure of the nasal mucosa with fibrin glue instead of standard suturing technique

Category

Treatment - Surgery

2**Description**

Control group: standard surgical treatment including the closure of the nasal mucosa with sutures

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Isfahan University of Medical Sciences

Full name of responsible person

Bijan Movahedian Attar

Street address

City
Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of medical sciences

Full name of responsible person

Zahra Fallah, GP, Research Assistant

Street address

Vice-Chancellery for Research(bldg no.4) ,Isfahan
University of medical sciences

City

Isfahan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Isfahan University of medical sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Bijan Movahedian Attar

Position

Associate professor, department of maxillofacial surgery

Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty
Analytic Code
empty

Data Dictionary
empty