

# 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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Isfahan dental school,Isfahan University of Medical Sciences

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## Person responsible for scientific inquiries

### Contact

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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*