# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

24 Jul 2026

## Evaluation of the success rate of alveolar bone grafts using fibrin glue

## Protocol summary

**Study aim**
Determination of bone volume formed after bone grafting to an alveolar defect in control and fibrin glue treatment groups, 4 months after surgery

**Design**
The study population is individuals with a unilateral alveolar cleft. According to the specific randomization method, the statistical population, which is a total of 20 people, is divided into two groups of intervention and control (each group has 10 patients).

**Settings and conduct**
This Single-blind clinical trial study will be performed on patients with unilateral alveolar clefts referred to Alzahra Hospital in Isfahan. The evaluators of the study results will be blind to the study groups. Patients in both groups are operated on according to standard surgical procedures for this type of disease, with the difference that in the intervention group, fibrin glue is also used. The results of fibrin glue are evaluated by a specialist using the cone-beam computed tomography (CBCT) method.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: 1. Presence of unilateral alveolar cleft, age 6 to 12 years 2. Conscious consent to participate in the study Exclusion criteria: 1. Bilateral alveolar cleft 2. Presence of systemic diseases or pathological disorders 3. History of chemotherapy or radiotherapy 4. Patients with a history of unsuccessful alveolar graft

**Intervention groups**
The study population is divided into two groups of intervention and the control group. In the control group, normal alveolar bone grafting is performed and in the intervention group, in addition to surgery, fibrin glue is also used.

**Main outcome variables**
The volume of bone formed after graft

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20210501051143N1**
Registration date: **2021-05-20, 1400/02/30**
Registration timing: **prospective**

Last update: **2021-05-20, 1400/02/30**
Update count: **0**

**Registration date**
2021-05-20, 1400/02/30

**Registrant information**

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Mohammad hossein Manouchehri naeini

**Name of organization / entity**

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Iran (Islamic Republic of)

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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2021-06-22, 1400/04/01

**Expected recruitment end date**
2021-08-23, 1400/06/01

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
Evaluation of the success rate of alveolar bone grafts using fibrin glue

**Public title**
Investigation the effect of fibrin glue on alveolar graft

**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Patients with unilateral alveolar cleft Ages 6 to 12 years referred to Al-Zahra Hospital in Isfahan Conscious consent to participate in the study
**Exclusion criteria:**
Bilateral alveolar cleft Presence of systemic diseases or pathological disorders History of chemotherapy or radiotherapy Patients with a history of unsuccessful alveolar transplantation
**Age**
From **6 years** old to **12 years** old
**Gender**
Both

**Phase**
N/A
**Groups that have been masked**

- Outcome assessor

**Sample size**
Target sample size: **20**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
In this study, patients were selected based on the inclusion and exclusion criteria of two-digit codes from 10 to 30, and randomization was performed based on the lottery method. Assignment codes were written on paper and placed inside an envelope. One of the researchers will pick up the written code without looking inside the envelope and will be assigned to the control group (A) or intervention group (B) alternatively. It should be noted that after removing each of the codes, in order to equalize the chances of all people, the read code will be placed again in the envelope, and in case of re-pick up an assigned code, it will be considered as an empty option.
**Blinding (investigator's opinion)**
Single blinded
**Blinding description**
Patients were randomly selected in such a way that they will be fully informed about the type of received treatment. Finally, the intervention effectiveness will be evaluated by the CBCT method compared to the control group. A specialist who is blind to the treatment procedures will assess the results, regardless of the control and intervention group, and report the results to each participant based on the assigned codes.
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

**1**

**Ethics committee**
**Name of ethics committee**
Research Ethics Committee of Isfahan University of Medical Sciences
**Street address**
Hezar Jerib St., Central Headquarters, Isfahan University of Medical Sciences and Health Services
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**Province**
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**Postal code**
8174673461
**Approval date**
2021-03-17, 1399/12/27
**Ethics committee reference number**
IR.MUI.RESEARCH.REC.1400.002

## Health conditions studied

**1**

**Description of health condition studied**
Unilateral alveolar cleft
**ICD-10 code**
K08.8
**ICD-10 code description**
Other specified disorders of teeth and supporting structures

## Primary outcomes

**1**

**Description**
The volume of bone formed after transplantation
**Timepoint**
Before surgery and 4 months after bone graft
**Method of measurement**
Cone beam computed tomography method

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
Control group: Includes ten patients with unilateral alveolar cleft who will undergo iliac crest bone graft surgery in the alveolar cleft area. After bone graft surgery, the nasal mucosa and palatal mucosa will be sutured.
**Category**
Treatment - Surgery

**2**

**Description**
Intervention group: Includes ten patients with unilateral alveolar cleft who will undergo iliac crest bone graft surgery in the alveolar cleft area. All interventions performed in this group will be completely similar to the control group, except for fibrin glue, which will be the only difference between the control group and the intervention group. After suturing the nasal mucosa and palatal mucosa, fibrin glue will be placed on the sutured part to prevent leaking bacteria into the transplant space.

**Category**
Treatment - Surgery

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**
Al-Zahra Medical Center - Isfahan University of Medical Sciences

**Full name of responsible person**
Bijan Movahedian Attar

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## Sponsors / Funding sources

**1**

**Sponsor**

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Esfahan University of Medical Sciences

**Full name of responsible person**
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**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**
No

**Title of funding source**
Isfahan 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

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**Position**
Professor

**Latest degree**
Specialist

**Other areas of specialty/work**
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## Person responsible for scientific inquiries

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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**
Yes - There is a plan to make this available
**Informed Consent Form**
Yes - There is a plan to make this available
**Clinical Study Report**
Yes - There is a plan to make this available
**Analytic Code**
Yes - There is a plan to make this available
**Data Dictionary**
Yes - There is a plan to make this available
**Title and more details about the data/document**
Information about participants, including sex, age, the volume of alveolar cleft, and the amount of bone formed after the intervention in both control and intervention groups, can be published after the individuals have not been identified.
**When the data will become available and for how long**
The access period is immediately after publication the results
**To whom data/document is available**
Only people working in health care institutions and medical researchers
**Under which criteria data/document could be used**
Researchers involved in the field related to this study, including evaluating the CBCT method to investigate bone volume or the effectiveness of fibrin glue in bone grafting
**From where data/document is obtainable**
Isfahan University of Medical Sciences, Department of Oral and Maxillofacial Surgery, School of Dentistry, Dr. Bijan Movahedian Attar, b_movahedian@dnt.mui.ac.ir
**What processes are involved for a request to access data/document**
The applicant must provide the required documentation from a valid institution to receive the files
**Comments**