# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 2026

## Evaluation of biological scaffold chondroblastic in shaping the junction of the nose in unilateral cleft lip and nose.

## Protocol summary

**Summary**

The purpose of this study is evaluation of biological scaffold chondroblastic in shaping the junction of the nose in unilateral cleft lip and nose. 40 children reffered to Hazrat Fatemeh hospital with unilateral cleft lip and nose deformity diagnostic in randomized double-blind without control with placebo and without trial phase with using sealed envelopes and on parallel divided into intrvention and control group. The patient must have age more than 10weeks, and weight morer than 10 kilogeram and patient over the age of 5 months will remove from study. In the intervention group, biological scaffolds with chondroblastic effect will used but in control group, scaffold is not used. Patients are followed for 6 months and then difference perimeter the 2 sides of the nose, the nose height, the width of the nose, tilt head of nose and weight will recorded in each group and compared with together.

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT2015071612642N15**
Registration date: **2015-08-22, 1394/05/31**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

**Registration date**

2015-08-22, 1394/05/31

**Registrant information**

**Name**
Majid Golestani Eraghi
**Name of organization / entity**
Shahid Beheshti University Of Medical Sciences
**Country**
Iran (Islamic Republic of)
**Phone**
+98 21 3336 0547
**Email address**
dr.golestani@arakmu.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

Vice chancellor for research, Iran University of Medical Sciences

**Expected recruitment start date**

2015-08-21, 1394/05/30

**Expected recruitment end date**

2016-03-20, 1395/01/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Evaluation of biological scaffold chondroblastic in shaping the junction of the nose in unilateral cleft lip and nose.

**Public title**

Effect of biological chondroblastic in shaping the junction of the nose

**Purpose**

Prevention

**Inclusion/Exclusion criteria**

Inclusion criteria: Hemoglobin more than 10; age greater than 12weeks; weight more than 10 kilogeram Exclusion criteria: Age more than five months; Lack of parent's consent

**Age**

From **3 months** old to **5 months** old

**Gender**

Both

**Phase**
N/A
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **40**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**
Randomization is performed using sealed envelopes.

## Secondary Ids

empty

## Ethics committees

**1**

**Ethics committee**
**Name of ethics committee**
Ethics Committee of Iran University of Medical Sciences
**Street address**
Hemmat Highway
**City**
Tehran
**Postal code**
**Approval date**
2015-05-26, 1394/03/05
**Ethics committee reference number**
2iums.REC.94.105.1222

## Health conditions studied

**1**

**Description of health condition studied**
effect of biological chondroblastic in shaping the junction of the nose
**ICD-10 code**
Q30.2
**ICD-10 code description**
Fissured, notched and cleft nose

## Primary outcomes

**1**

**Description**
Between the two sides of the nose
**Timepoint**
Up to 6 months after surgery and at intervals of 3 months
**Method of measurement**
With millimeters using Adobe Photoshop

**2**

**Description**
The height of the nose
**Timepoint**
Up to 6 months after surgery and at intervals of 3 months
**Method of measurement**
With millimeters using Adobe Photoshop

**3**

**Description**
The width of the nose
**Timepoint**
Up to 6 months after surgery and at intervals of 3 months
**Method of measurement**
With millimeters using Adobe Photoshop

## Secondary outcomes

**1**

**Description**
Deviation of the nasal
**Timepoint**
Up to 6 months after surgery and at intervals of 3 months
**Method of measurement**
with degree scale using Adobe Photoshop

**2**

**Description**
weight
**Timepoint**
before surjery
**Method of measurement**
Using digital scales and scale kilogeram

## Intervention groups

**1**

**Description**
The first group, biological scaffolds made of poly dioxonane made by Mentor company are used
**Category**
Prevention

**2**

**Description**
The second group is the control group received no interventionand biological scaffolds are not used
**Category**
Prevention

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Hazrat Fatemeh Hospital
**Full name of responsible person**
Majid Golestani Eraghi
**Street address**
Beside of Shafagh Park, Asadabadi Ave
**City**
Tehran

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Vice chancellor for research, Iran University of Medical Sciences
**Full name of responsible person**
Seyed Alijavad Musavi
**Street address**
Vice chancellor for research, Hemmat Highway
**City**
Tehran
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Vice chancellor for research, Iran 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**

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Departman of Surgery, Iran University Of Medical Science
**Full name of responsible person**
Kamran Asadi
**Position**
Specialty Plastic Surgery
**Other areas of specialty/work**
**Street address**
Hazrat Fatemeh Hospital, Beside of Shafagh Park, Asadabadi Ave
**City**
Tehran
**Postal code**
**Phone**
+98 88717272
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**Email**
asadi_kamran@tums.ac.ir
**Web page address**

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Anesthesia group, Shahid Beheshti University of Medical Sciences
**Full name of responsible person**
Majid Golestani Eraghi
**Position**
Fellowship specialty intensive care
**Other areas of specialty/work**
**Street address**
Darabad ave
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+98 21 2712 2525
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dr.golestani@sbmu.ac.ir
**Web page address**

## 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*