

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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 referred 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 intervention and control group. The patient must have age more than 10 weeks, and weight more than 10 kilogram and patient over the age of 5 months will remove from study. In the intervention group, biological scaffolds with chondroblastic effect will be 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 be 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 12 weeks; weight more than 10 kilogram 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 surgery

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 intervention and 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**

Department 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

Fax**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

City

Tehran

Postal code**Phone**

+98 21 2712 2525

Fax**Email**

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