

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Comparison of the effect of bone increment technique and osteotomy on frontoorbital deformity in patients with non-syndromic craniosynostosis

Protocol summary

Study aim

Study aim is the comparison of the effect of bone increment technique and osteotomy on frontoorbital deformity in patients with non-syndromic craniosynostosis.

Design

Two arm parallel group, randomized, controlled clinical trial on 10 patients. Simple randomization was used.

Settings and conduct

This study will be conducted in 2022 and in Imam Hossein Children Hospital in Isfahan. In this study, blinding was not done, and patients were randomly divided into intervention and control groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Patients with non-syndromic simple coronal suture craniosynostosis, 2. Patients with non-syndromic simple metopic suture craniosynostosis
Exclusion criteria: 1. Lack of informed consent of parents, 2. Presence of any underlying disease that is a contraindication for surgery, 3. Previous history of skull surgery

Intervention groups

Intervention group: The bone increment technique without common complications will be used. Control group: The classic osteotomy method with known complications will be used.

Main outcome variables

Correction of deformity of the forehead and orbit

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220816055722N1**

Registration date: **2022-12-03, 1401/09/12**

Registration timing: **registered_while_recruiting**

Last update: **2022-12-03, 1401/09/12**

Update count: **0**

Registration date

2022-12-03, 1401/09/12

Registrant information

Name

Ata Mahdkhah

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3662 4589

Email address

amahdkhah@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-06, 1401/06/15

Expected recruitment end date

2022-12-06, 1401/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of bone increment technique and osteotomy on frontoorbital deformity in patients with non-syndromic craniosynostosis

Public title

Correction of forehead and orbit deformities in patients with non-syndromic craniosynostosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with non-syndromic simple coronal suture
 craniosynostosis Patients with non-syndromic simple
 metopic suture craniosynostosis

Exclusion criteria:

Lack of informed consent of parents The presence of any
 underlying disease that is a contraindication for surgery
 Previous history of skull surgery

Age

From **3 months** old to **3 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **10**

Randomization (investigator's opinion)

Randomized

Randomization description

We used simple, individual randomization and random
 number table randomization. Random number table is a
 set of numbers that are generated without a specific
 pattern or order and in a completely random manner and
 become a table. First, we selected 10 two-digit numbers
 according to the number of people studied, and among
 these numbers, 5 numbers were randomly selected from
 the table and were used as the intervention group. The
 rest numbers were considered as the control group. In
 order to use the table of random numbers, we first
 predetermined the table to read the numbers, then we
 considered the numbers for different groups, then we
 touched one of the numbers and moved in one of the
 predefined directions and recorded the numbers.

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 Medical Faculty of Isfahan
 University of Medical Sciences

Street address

No. 4, Isfahan University of Medical Sciences, Hezar
 Jerib Ave; Telephone:03137923084

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2022-07-17, 1401/04/26

Ethics committee reference number

IR.MUI.MED.REC.1401.160

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

Craniosynostosis

ICD-10 code

Q75.0

ICD-10 code description

Craniosynostosis

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

Correction of deformity of the forehead and orbit

Timepoint

Before intervention and three months after intervention

Method of measurement

CT Scan

Secondary outcomes

empty

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

Intervention group: Bone increment technique will be
 used in 5 patients. This method is an innovative method
 to reduce the known complications of classic approach.
 There is a lower rate of hemorrhage and nerve injury in
 this method. Fibular bone graft will be used to reshape
 the orbitofrontal deformity. Remodeling will be based on
 the severity of deformity. We will use imaging for
 postoperative evaluation. The patient will be visited at
 least 3 times.

Category

Treatment - Surgery

2**Description**

Control group: 5 patients will be treated with classic
 osteotomy technique. In this method, there is a high
 probability of hemorrhage and air emboli. Orbitofrontal
 deformity will be corrected using osteotomy. We will use
 imaging for postoperative evaluation. The patient will be
 visited at least 3 times.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Children Hospital

Full name of responsible person

Ali Riazi

Street address

Imam Hossein Children Hospital, Imam Khomeini Avn

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Gholamreza Asgari

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No. 4, Isfahan University of Medical Sciences, Hezar-jarib Avn

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Esfahan 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

Full name of responsible person

Ali Riazi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Neurosurgery

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Person responsible for scientific inquiries

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Full name of responsible person

Ali Riazi

Position

Assistant Professor

Latest degree

Specialist

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Person responsible for updating data

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Position

Fellowship

Latest degree

Specialist

Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available