

# 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

**City**

Isfahan

**Province**

Isfahan

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8195163381

**Phone**

+98 31 3386 6266

**Email**

emamHosseinChildren'sHospital@mui.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Gholamreza Asgari

**Street address**

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

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research@mui.ac.ir

**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

#### 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 updating data

#### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Ata Mahdkhah

**Position**

Fellowship

**Latest degree**

Specialist

**Other areas of specialty/work**

Neurosurgery

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**Email**

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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