Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of esthetic and anthropometric outcomes of frontorbital correction for non-syndromic anterior plagiocephaly by modified z technique of temporal region osteotomy in 15khordad and Mofid hospitals during 2022-2024

Protocol summary

Study aim

Evaluation of aesthetic and anthropometric outcomes of frontorbital correction for non-syndromic anterior plagiocephaly by modified z technique of temporal region osteotomy

Design

A quasi-experimental, before-and-after, double-blind, non-randomized, clinical trial study will be conducted on 49 patients with non-syndromic anterior plagiocephaly who will undergo surgery with the modified z-technique of temporal region osteotomy. According to this study, it will be before and after, the randomization process will not be used in this study. Outcome and skull anthropometric measurements will be measured before and 3 months after surgery. Participants or their parents and the data analyst will be blinded to the type of surgical technique.

Settings and conduct

In this clinical trial before and after study, patients with non-syndromic anterior plagiocephaly who will be operated on in the period of January 2024 and June 2024 in Panzdeh Khordad and Mofid Hospitals in Tehran with the modified z-technique of temporal region osteotomy will be investigated. .

Participants/Inclusion and exclusion criteria

The inclusion criteria will include anterior plagiocephaly and infants with an age range of 2 to 24 months. Suffering from genetic diseases such as hemophilia and Down's syndrome, history of previous skull surgery, secondary anterior plagiocephaly, and lack of consent to participate in the study were defined as exclusion criteria.

Intervention groups

Fronto-orbital advancement surgery on patients with non-syndromic anterior plagiocephaly with modified Z osteotomy technique

Main outcome variables

Aesthetic score and changes in anthropometric parameters of the skull

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110522006552N3**
Registration date: **2024-01-23, 1402/11/03**
Registration timing: **registered_while_recruiting**

Last update: **2024-01-23, 1402/11/03**
Update count: **0**

Registration date

2024-01-23, 1402/11/03

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8890 1108

Email address

esmail_hassanpour@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-21, 1402/11/01

Expected recruitment end date

2024-06-23, 1403/04/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of esthetic and anthropometric outcomes of frontorbital correction for non-syndromic anterior plagiocephaly by modified z technique of temporal region osteotomy in 15khordad and Mofid hospitals during 2022-2024

Public title

the outcome of fronto-orbital advancement in patients with non-syndromic anterior plagiocephaly

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Written informed consent to undergo the surgical procedure Patients with anterior plagiocephaly were referred to the clinic in 15 Khordad and Mofid hospitals in Tehran between 2021 and 2023. According to the opinion of the plastic surgeon, patients with craniosynostosis who are candidates for correction with front orbital advancement.

Exclusion criteria:

Multi- suture craniosynostosis Syndromic craniosynostosis

Age

From **3 months** old to **24 months** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **49**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the parents of the patients were informed about the type of technique used in the operation, because the surgical technique is different only during the operation, and after the surgery is completed and the suture is applied, the size and shape of the incision is similar to the routine surgery, and only the surgeon is aware of the nature of the procedure. The surgery is informed. The outcome assessors did not know about the technique used in the operation in presenting their opinions about the efficiency of the operation result. In post-operative visits, the surgeon did not know the type of technique to present his opinion on the result of each patient's operation.

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of shahid Beheshti University of Medical Sciences

Street address

Floor 13, Block A, Ministry of Health& Medical Education Headquarters, Between Zarafashan & South Falamak, Qods Town, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1989934148

Approval date

2023-06-27, 1402/04/06

Ethics committee reference number

IR.SBMU.MSP.REC.1402.142

Health conditions studied

1

Description of health condition studied

Patients with Non- syndromic anterior plagiocephaly

ICD-10 code

Q67.3

ICD-10 code description

Congenital malformations and deformations of the musculoskeletal system

Primary outcomes

1

Description

Surgical and aesthetic satisfaction score

Timepoint

Before surgery and 3 months after intervention (surgery)

Method of measurement

Satisfaction level questionnaire

2

Description

anthropometric skull measurements

Timepoint

Before surgery and 6 months after intervention (surgery)

Method of measurement
Using a graduated ruler

Secondary outcomes

1

Description
Recurrence of deformity after surgery
Timepoint
12 month after intervention
Method of measurement
Physical Examination

Intervention groups

1

Description
Intervention group: For all patients with non-syndromic plagiocephaly, a coronal incision is first given so that the frontal bone can be moved after the flap is raised and turned down to 5 cm above the rim of the orbit, the flap is raised subperiosteally to the edge of the rim so that the supraorbital and supratrochlear nerves are not damaged. After correcting the shape of the skull and forehead on the head with a suitable design, the osteotomy of the upper region of the orbit and its continuation to the temporal region is performed as a z-osteotomy. Bone incisions and breaking the bone in the form of (Barrel Stave) are performed to correct the narrowing of the frontal area and the deformities in the frontal bone parts above the orbit and the upper part of the frontal bone separately. The repositioning of the upper parts of the eyeball is done as an approximation, and absorbable screws and plates are used to fix the bone parts. In temporal osteotomy, the 2 edges of the bone site are placed together in a z-shape so that there is less defect and no need for bone graft, and there is no possibility of the bone piece sliding or returning after fixing. After fixing the bone with screws and plates and reaching the desired shape, and sufficient hemostasis and drain placement, then the scalp flap is returned to its place, and its layers are repaired.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
15 Khordad Hospital
Full name of responsible person
Seyed Esmail Hassanpour
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15 Khordad Hospital, South Azodi St, Karim Khan Zand Blvd, Tehran, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
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Position

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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
All demographic data and primary and secondary outcome information after de-identification of shareable subjects
When the data will become available and for how long
The access period starts 6 months after the results are published
To whom data/document is available
Data and other documentation will be available to researchers working in academic and scientific institutions
Under which criteria data/document could be used
After publishing the results in the form of an article, the data will be available for researchers to design the study by providing a logical reason to the correspondence author with the condition of maintaining ethical principles. Also, the data will be available if requested by the ethics committee of the university to evaluate the accuracy of the results.
From where data/document is obtainable
Applicants can refer to Dr. Mehran Nouri, Assistant Specialist in Plastic Surgery, Shahid Beheshti University of Medical Sciences, to receive the required documents and data. Address: Tehran, Karim Khan Zand St., at the beginning of Shahid Dr. Azdi St. Postal code 1598764514 Email: mehrannoori64@yahoo.com Phone: 09122025141
What processes are involved for a request to access data/document
Applicants must follow the protocols and procedures according to Shahid Beheshti University of Medical Sciences rules to access the desired files

Comments