

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 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

Street address

15 Khordad Hospital, South Azodi St, Karim Khan Zand Blvd, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1598764514

Phone

+98 21 8891 3434

Email

Hassanpour1394@sbmu.ac.ir

Web page address

<https://pkmc.sbmu.ac.ir>

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Seyed Ali Ziaei

Street address

Shahid Beheshti University of Medical Sciences< Velenjack, Shahid Chamran Highway, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

19839-63113

Phone

+98 21 2243 9770

Email

intl_office@sbmu.ac.ir

Web page address

<https://remsp.sbmu.ac.ir/>

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

Full name of responsible person

Mehran Noori

Position

Specialist assistant

Latest degree

Specialist

Other areas of specialty/work

Plastic Surgery

Street address

Tehran - Shahid Chamran Highway, Yemen Street -
Shahid Arabi Street, next to Ayatollah Taleghani
Hospital

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 2243 9982

Email

mehrannoori64@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Seyed Esmail Hassanpour

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Plastic Surgery

Street address

15 Khordad Medical, Educational and Therapeutic
Center, Dr. Azdi St. (first of Aban South), Karim Khan
Zand St. Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1598764514

Phone

+98 21 8894 3434

Email

Hassanpour1394@sbmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mehran Noori

Position

Specialist assistant

Latest degree

Specialist

Other areas of specialty/work

Plastic Surgery

Street address

5 Khordad Medical, Educational and Therapeutic
Center, South Aban, Karim Khan Zand St, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1598764514

Phone

0098 21 8891 34343

Email

mehrannoori64@yahoo.com

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