

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of therapeutic safety and efficacy of tranexamic acid or aprotinin in absolute blood loss and transfusion in pediatric patients undergoing craniosynostosis surgery

Protocol summary

Study aim

□ To determine average absolute blood loss in each three groups and comparison between groups

Design

In the current randomized controlled trial, 90 eligible pediatric patients with craniosynostosis will be randomly divided into 3 intervention groups to receive aprotinin 35000 KIU/kg with 10000 KIU/kg/h infusion rate intraoperative, tranexamic acid 50 mg/kg intravenously intraoperative, or no intervention. The absolute blood loss and transfusion will be assessed for all patients both intraoperative, 24 hours, and 48 hours postoperative.

Settings and conduct

A randomized, single center, parallel, double blind, superiority controlled trial to compare therapeutic safety and efficacy of tranexamic acid or aprotinin in absolute blood loss and transfusion in pediatric patients undergoing craniosynostosis surgery

Participants/Inclusion and exclusion criteria

Pediatric patients between ages 2 months to 2 years, of both sexes, with single of multiple suture craniosynostosis and hemoglobin level of more than 13 mg/dl, without history of coagulopathies, hemoglobinopathies, abnormal renal function tests, allergy to intervention drugs will be included in this study..

Intervention groups

Tranexamic acid, Aprotinin, No intervention

Main outcome variables

Primary objectives: Intraoperative and postoperative blood loss and blood transfusion and intervention-related mortality will be considered as primary outcomes
Secondary objectives: Mean difference of immediate, 24-hour, and 48-hour postoperative Hb and Hct subtracted from preoperative levels, coagulation test abnormality, diffuse intravascular coagulation (DIC), acute renal failure, acute tubular necrosis, all case mortality, and

adverse events will be considered as secondary objectives.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200705048023N1**

Registration date: **2020-07-07, 1399/04/17**

Registration timing: **prospective**

Last update: **2020-07-07, 1399/04/17**

Update count: **0**

Registration date

2020-07-07, 1399/04/17

Registrant information

Name

Zahra Ebrahim Soltani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4421 0127

Email address

zahra_esoltani@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-22, 1399/05/01

Expected recruitment end date

2020-12-20, 1399/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of therapeutic safety and efficacy of tranexamic acid or aprotinin in absolute blood loss and transfusion in pediatric patients undergoing craniosynostosis surgery

Public title
Effect of tranexamic acid and aprotinin in absolute blood loss in pediatric neurosurgery

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
☐ Age between 2 months and 2 years, both sex ☐ Single or multi-suture craniosynostosis including metopic, sagittal, unicoronal, and bicoronal synostoses ☐ Syndromic or non-syndromic craniosynostosis ☐ Hemoglobin level of equal or more than 13 mg/dl ☐ Patient's parents or legal guardian agreement to sign the informed consent form
Exclusion criteria:
☐ Indication for endoscopic craniosynostosis surgery ☐ History of coagulopathies or hemoglobinopathies in patient or first degree family (hemophilia, abnormal PT, PTT, INR tests, afibrinogenemia, congenital coagulopathy factor deficiencies) ☐ Craniofacial surgeries ☐ Craniosynostosis recurrence ☐ Secondary craniosynostosis ☐ Abnormal renal function tests including abnormal BUN and Cr for age or family history of hereditary renal disease as polycystic kidney ☐ Allergy to Aprotinin, tested 30 minutes pre operation with 0.1 dose of therapeutic dose ☐ Congenital heart disease

Age
From **2 months** old to **2 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization: The order of study interventions would be determined using 6-block computer-based randomization master list. (<http://randomization.ir>)
Random allocation: The intervention for each patient would be determined accordingly to randomization cards and their orders would be accordingly to randomization master list. Concealment: The randomization cards would be placed in opaque pockets and only in time of random allocation, one pocket would be opened for one patient.

Blinding (investigator's opinion)
Double blinded

Blinding description
each patient will allocated to one of 3 groups randomly. the randomization will performed by a separate research team (without informing the surgeon, anesthesiologist and personnel of operation room. the prescription of the drug will performed by anesthesiology service (without informing the surgeon from the intervention group). the assessment during surgery will done by surgical service and the assessment after surgery will performed by ICU service (without informing the surgeon from the intervention group).

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees
1
Ethics committee
Name of ethics committee
ethics committee of Children Medical Center
Street address
Children Medical Center, Qarib street
City
tehran
Province
Tehran
Postal code
1419733151
Approval date
2020-07-04, 1399/04/14
Ethics committee reference number
IR.TUMS.CHMC.REC.1399.061

Health conditions studied

1
Description of health condition studied
craniosynostosis
ICD-10 code
ICD-10 code description

Primary outcomes

1
Description
Intraoperative and postoperative blood loss and blood transfusion and intervention-related mortality will be considered as primary outcomes
Timepoint
during the surgery, 4 and 24 hours after surgery
Method of measurement
The amount of blood loss as the result of surgery,

intraoperative or postoperative. Estimation or calculation with formula

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Tranexamic acid

Category

Treatment - Drugs

2

Description

Intervention group: Aprotinin

Category

Treatment - Drugs

3

Description

Control group: No intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Children Medical Center (CMC)

Full name of responsible person

Zahra Ebrahim soltani

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Qarib street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

mohammad reza monazam

Street address

Keshavarz blvd, pour-sina street

City

Tehran

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Email

irsw-leadinghouse@tums.ac.ir

Web page address

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Zahra Ebrahim soltani

Position

medical student

Latest degree

A Level or less

Other areas of specialty/work

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Person responsible for updating data

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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

Not applicable

Informed Consent Form

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

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable