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 coagulatory 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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
mohammad reza monazam
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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
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Position
medical student
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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