Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jul 2026

Comparison of tranexamic acid administration and controlled hypotension or combination of them for bleeding reduction during craniocynostosis surgery in Imam Hossein Hospital in Isfahan in 2016-17

Protocol summary

Study aim

The assessment of the efficacy of tranexamic acid and controlled hypotension or a combination of both for the reduction in bleeding during craniosynostosis surgery

Design

Randomized double-blinded clinical trial without control group, with parallel-groups

Settings and conduct

The study will be conducted in Imam Hossein Hospital on infants who meet the inclusion criteria and are a candidate for craniosynostosis surgery under general anesthesia. Before the anesthesia induction, two venous lines were taken and blood transfusion will be initiated. Immediately following anesthesia induction in a similar pattern of 0,02mg/kg atropine, 5mg/kg sodium thiopental and 0.5mg/kg atracurium, the interventions will be done. The legal guardians of the patients will be blinded to the type of intervention. Besides, the investigator who should gather the data in the study checklist will be blinded, as well.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Physical status of ASA I-II based on American Society of Anesthesiology Unmet criteria: - Cardiac disease - Liver diseases - Renal diseases - Pulmonary diseases -Congenital anomalies

Intervention groups

The first intervention group: 10mg/kg tranexamic acid The second intervention group: Controlled hypotension at mean arterial pressure of 30mmHG less than what was measured before anesthesia induction or in range of 50-60mmHG The third intervention group: 10mg/kg tranexamic acid plus controlled hypotension at mean arterial pressure of 30mmHG less than what was measured before anesthesia induction or in range of 50-60mmHG

Main outcome variables

Amount of bleeding; Amount of transfused blood and fresh frozen plasma; Duration of intensive care unit admission

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190328043128N1**
Registration date: **2020-03-04, 1398/12/14**
Registration timing: **retrospective**

Last update: **2020-03-04, 1398/12/14**
Update count: **0**

Registration date

2020-03-04, 1398/12/14

Registrant information

Name

Zahra Mazaheri Tehrani

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 31 3225 9771

Email address

zahra.mzht@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-03-21, 1396/01/01

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

2017-05-10, 1396/02/20

Actual recruitment end date

2018-04-22, 1397/02/02

Trial completion date

2018-05-02, 1397/02/12

Scientific title

Comparison of tranexamic acid administration and controlled hypotension or combination of them for bleeding reduction during craniocynostosis surgery in Imam Hossein Hospital in Isfahan in 2016-17

Public title

Tranexamic acid, controlled hypotension or their combination for reduction in bleeding due to craniocynostosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Physical status of I-II based on American Society of Anesthesiology Age of 3 months to 12 months

Exclusion criteria:

Cardiac disease Liver disease Renal disease Pulmonary disease Congenital anomaly

Age

From **3 months** old to **12 months** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **75**

Actual sample size reached: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

Each of the patients was provided with a particular number by Random Allocation software allocated them to an intervention group. Each patient was provided with a particular number. Cases with numbers corresponded for 3*k were allocated to tranexamic acid treated group, those with numbers corresponded for 3*k+1 were allocated to controlled hypotension group and those with numbers corresponded for 3*k+2 were allocated to the groups treated with the combination of tranexamic acid and controlled hypotension

Blinding (investigator's opinion)

Double blinded

Blinding description

The legal guardians of the patients will be blinded to the intervention and the researcher who records the information will be blinded as well.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

Street address

Hezar Jarib Street

City

Isfahan

Province

Isfehan

Postal code

8174673461

Approval date

2017-05-31, 1396/03/10

Ethics committee reference number

IR.MUI.REC.1396.3.597

Health conditions studied

1

Description of health condition studied

Bleeding during craniosynostosis

ICD-10 code

Q75.0

ICD-10 code description

Craniosynostosis

Primary outcomes

1

Description

Amount of bleeding

Timepoint

During the surgery

Method of measurement

Gradient container contained suctioned blood

2

Description

The amount of transfused blood

Timepoint

During the surgery and admission at intensive care unit

Method of measurement

Pack cell

3

Description

The amount of transfused fresh frozen plasma

Timepoint

During the surgery and admission at intensive care unit

Method of measurement
Pack cell

Secondary outcomes

empty

Intervention groups

1

Description
The first Intervention group: Tranexamic acid; 10 mg/kg; Immediately after anesthesia induction
Category
Treatment - Drugs

2

Description
The second Intervention group: Controlled hypotension; The manipulation of mean arterial pressure at 30 mmHg less than mean arterial pressure before the anesthesia induction or regulation of mean arterial pressure at 50-60 mmHg; Immediately after anesthesia induction
Category
Treatment - Other

3

Description
The third Intervention group: Combination of Tranexamic acid with controlled hypotension; 10 mg/kg of tranexamic acid plus the manipulation of mean arterial pressure at 30 mmHg less than mean arterial pressure before the anesthesia induction or regulation of mean arterial pressure at 50-60 mmHg; Immediately after anesthesia induction
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hossein Hospital
Full name of responsible person
Amir Shafa
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Hezarjarib Street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Mozhgan Mortazavi
Street address
Hezarjarib Street, Isfahan University of Medical Sciences, Vice chancellor for research
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Phone
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Email
mortazavi@med.mui.ac.ir
Web page address
http://med.mui.ac.ir/?q=pajoheshi/pajoheshi
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Isfahan University of Medical Sciences, Vice chancellor for Research affiliated at Isfahan 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
Amir Shafa
Position
Assistant professor
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Specialist
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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
The data of the present study are provided by the relevant professor and in the case of publishing new and related studies are provided
When the data will become available and for how long
Following the publication of the article in an international journal, the data are acceible
To whom data/document is available
Residents of anesthesiology who have a new proposal in this regard with the similar professor
Under which criteria data/document could be used
Only for publication of a new article with the relevant professor
From where data/document is obtainable
With the relevant anesthesiologist
What processes are involved for a request to access data/document
Following a call or an email to the relevant professor
Comments