

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of preoperative intravenous tranexamic acid on hemorrhage in patients who undergoing cleft palate reconstruction surgery

Protocol summary

Summary

Randomized study evaluating the effect tranexamic acid on hemorrhage in cleft palate reconstruction surgery. Double-blind randomized study comparing intraoperative bleeding in palatoplasty between patients who received tranexamic acid at a dose of 10 mg/kg bolus followed by continuous infusion of 1 mg/kg/h until the end of the procedure and patients receiving placebo in similar arrangements. Besides the impact on the volume of intraoperative bleeding and operative duration and the incidence of postoperative blood transfusion and reoperative hemostasis were evaluated. Inclusion Criteria: Palatoplasty indication in patients with presence of congenital cleft palate (with or without associated cleft lip). Exclusion Criteria: Preoperative hemoglobin lower than 10 mg/dl or platelet count less than 100,000/mm³ ; Presence of coagulopathy caused by known coagulation cascade disorders or systemic diseases, or excessive bleeding history on previous occasions; History of bleeding disorders in first-degree relatives; Use of medications that may interfere with the coagulation cascade (platelet inhibitors or anticoagulants); Indication of secondary palatoplasty with the purpose of correction oro-nasal fistula; Known allergy to tranexamic acid; History of hematuria.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015112325208N1**
Registration date: **2016-01-17, 1394/10/27**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-01-17, 1394/10/27

Registrant information

Name

Motalleb Salehpour

Name of organization / entity

Zahedan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 910 443 5309

Email address

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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2015-12-22, 1394/10/01

Expected recruitment end date

2016-08-22, 1395/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of preoperative intravenous tranexamic acid on hemorrhage in patients who undergoing cleft palate reconstruction surgery

Public title

The effect tranexamic acid on hemorrhage in cleft palate reconstruction surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Palatoplasty indication in patients with presence of congenital cleft palate (with or without associated cleft lip). Exclusion Criteria: Preoperative

hemoglobin lower than 10 mg/dl or platelet count less than 100,000/mm³; Presence of coagulopathy caused by known coagulation cascade disorders or systemic diseases, or excessive bleeding history on previous occasions; History of bleeding disorders in first-degree relatives; Use of medications that may interfere with the coagulation cascade (platelet inhibitors or anticoagulants); Indication of secondary palatoplasty with the purpose of correction oro-nasal fistula; Known allergy to tranexamic acid; History of hematuria.

Age

From **1 year** old to **12 years** old

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Patients will be randomized into the study and randomly using randomized block into a control group or to be investigation group(Double-blind randomized study).

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Zahedan University of Medical Sciences

Street address

Integrating the campus of the University of Medical Sciences

City

Zahedan

Postal code

9816743463

Approval date

2015-11-08, 1394/08/17

Ethics committee reference number

IR.ZAUMS.REC.13940300

Health conditions studied

1

Description of health condition studied

cleft palate with or without cleft lip

ICD-10 code

Q35,Q37

ICD-10 code description

Cleft palate, Cleft palate with cleft lip

Primary outcomes

1

Description

intraoperative bleeding

Timepoint

during surgery

Method of measurement

Intraoperative bleeding volume defined as the sum of the volume blood in the suction during the procedure and the volume of blood retained in the used gauze

2

Description

operative duration

Timepoint

since anesthesia induction until patient exited from operation room

Method of measurement

Data collection form

Secondary outcomes

1

Description

Hemoglobin(Hb)

Timepoint

6 hour after procedure

Method of measurement

Data collection form

2

Description

bleeding requiring reoperative homeostasis

Timepoint

post operation

Method of measurement

Data collection form

Intervention groups

1

Description

Control: patients before incision received placebo(normal saline) acid at a dose of 10 mg/kg bolus followed by continuous infusion of 1 mg/kg/h until the end of the procedure.

Category

Placebo

2

Description

Intervention: patients before incision received tranexamic acid (Caspian Tamin Pharmaceutical Co.) at a dose of 10 mg/kg bolus followed by continuous infusion of 1 mg/kg/h until the end of the procedure.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Khatamolanbia Hospital

Full name of responsible person

Gholam Ali Dashti Khavidaki

Street address

ENT clinic of Khatamolanbia Hospital

City

Zahedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Zahedan University of Medical Sciences

Full name of responsible person

Gholam Ali Dashti Khavidaki

Street address

ENT clinic of Khatamolanbia Hospital

City

Zahedan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for research of Zahedan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Gholam Ali Dashti Khavidaki

Position

Board in Otorhinolaryngology

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Gholam Ali Dashti Khavidaki

Position

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

motalleb salehpour

Position

Medical student

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty