

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the intravenous tranexamic acid effect on blood loss and surgical field quality during nasal surgery

Protocol summary

Summary

Aim: Evaluation of the intravenous tranexamic acid effect on blood loss and surgical field quality during nasal surgery. Design: Double blinded randomized controlled trial. Setting: The eligible patients with nasal surgery who will refer to ENT clinic of Besat hospital in 2013. Inclusion criteria: (a) patients with nasal surgery; (b) age of 18 to 75 years; (c) ASA $\leq$ II. Exclusion criteria: (a) Patient refuse; (b) abnormal coagulation test; (c) surgery time less than 30 minutes (d) history of thrombosis or deep vein thrombosis; (e) acute or chronic renal failure; (f) ischemic heart disease and arrhythmia; (g) history of seizure; (h) allergy to tranexamic acid; (i) usage herbal medications; (j) pregnancy; (k) color blind. Intervention: During nasal operation 35 patients will receive 500 mg intravenous tranexamic acid mixed up in 500ml lactated Ringer's solution with concentration 1mg/ml and maximum infusion rate 100mg/min and maximum dosage 15mg/kg. Control: During nasal operation 35 patients will receive lactated Ringer's solution as maintenance therapy. Primary outcome: (a) quality of surgical field every 20 minutes during surgery using Boezart scale; (b) determine blood volume accumulated in the suction chamber after operation; (c) changes hemoglobin and hematocrit 6 hours after surgery; (d) satisfactory of surgeon at end of operation. Secondary outcome: measurement of (a) seizure; (b) nausea; (c) vomiting; (d) and impaired color vision 24 hours after surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013012911822N3**

Registration date: **2013-03-09, 1391/12/19**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-03-09, 1391/12/19

Registrant information

Name

Behrooz Karkhanei

Name of organization / entity

Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0574

Email address

karkhanei@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for Research and Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2013-02-19, 1391/12/01

Expected recruitment end date

2013-08-22, 1392/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the intravenous tranexamic acid effect on blood loss and surgical field quality during nasal surgery

Public title

Evaluation of the intravenous tranexamic acid effect on blood loss and surgical field quality during nasal surgery

Purpose

Treatment

Inclusion/Exclusion criteria
 Inclusion criteria: Nasal surgery; 18 to 65 years old; ASA ≤ II
 Exclusion criteria: Patient refuse; Surgery time less than 30 minutes; Renal dysfunction; Impaired color vision; Abnormal coagulation test; History of thrombosis or deep vein thrombosis; Ischemic heart disease and arrhythmia; Central nerve system disorder; Allergy to tranexamic acid; Usage Herbal medications; Pregnancy

Age
 From **18 years** old to **65 years** old

Gender
 Both

Phase
 N/A

Groups that have been masked
No information

Sample size
 Target sample size: **70**

Randomization (investigator's opinion)
 Randomized

Randomization description

Blinding (investigator's opinion)
 Double blinded

Blinding description

Placebo
 Used

Assignment
 Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Local Human Subject Review Board

Street address

Shaheed Famideh Street, Hamadan University Of Medical Sciences

City

Hamadan

Postal code

6517838695

Approval date

2013-02-14, 1391/11/26

Ethics committee reference number

D/P/16/35/9/4021

Health conditions studied

1

Description of health condition studied

heamorrhage

ICD-10 code

Y60.0

ICD-10 code description

Unintentional cut, puncture, perforation or haemorrhage during surgical and medical care During surgical operation

Primary outcomes

1

Description

volume of blood in suction bottle

Timepoint

At end of surgery

Method of measurement

Viewing chamber volume per ml

2

Description

Quality of hemorrhage

Timepoint

each 20 min.

Method of measurement

Boezzart criteria

3

Description

Hematocrit

Timepoint

Preoperative and six hours postoperative

Method of measurement

Automated Cell Counter

4

Description

hemoglobin

Timepoint

Preoperative and six hours postoperative

Method of measurement

Automated Cell Counter

5

Description

Satisfactory of surgeon from bleeding

Timepoint

At end of surgery

Method of measurement

ask the surgeon

Secondary outcomes

1

Description

impaired color vision

Timepoint

the day after sugery

Method of measurement

Ask the patient

Hamadan

2

Description

Nausea

Timepoint

The day after surgery

Method of measurement

Ask the patient

3

Description

Vomiting

Timepoint

The day after surgery

Method of measurement

Ask the patient

4

Description

Seizure

Timepoint

The day after surgery

Method of measurement

observation of the patient

Intervention groups

1

Description

During nasal operation, patients will receive 500 mg intravenous tranexamic acid mixed up in 500ml lactated Ringer's solution with concentration 1mg/ml and maximum infusion rate 100mg/min and maximum dosage 15mg/kg.

Category

Treatment - Drugs

2

Description

During nasal operation, control patients will receive lactated Ringer's solution as maintenance therapy.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital

Full name of responsible person

Behrooz Karkhanei

Street address

Besat Hospital, Imam Hossein Square

City

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for Research and Technology,
Hamadan University of Medical Science

Full name of responsible person

Ahmad Tavalani

Street address

Hamadan University of Medical Sciences, Vice
chancellor for Research and Technology, Shaheed
Fahmideh St.

City

Hamadan

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 and Technology, Hamadan
University of Medical Science

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

Hamadan University of Medical sciences

Full name of responsible person

Behrooz Karkhanei

Position

MD. Assistant Professor of Anesthesiology

Other areas of specialty/work

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Salahaddin ghaderi

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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