

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

The effect of Tranexamic Acid in decreasing of intraoperative bleeding and need for deliberate hypotension in patients undergoing Functional Endoscopic Sinus Surgery.

Protocol summary

Summary

The aim of this study is determining the effect of tranexamic acid to reduce intraoperative bleeding in patients undergoing endoscopic sinus surgery. This is a randomized double-blind with a placebo control study . All 16 to 40 years old patients with ASA class 1 in Ahwaz Imam Khomeini hospital that candidate for elective Functional Endoscopic Sinus Surgery are studied. Exclusion criteria were pregnancy and coagulopathy disorders.The sample in this study were calculated 66 patients .Bleeding Calculate by the number of gases and blood soaked into the suction .Patients divided into two groups.Immediately after induction,in case group we infuse 10mg/kg Tranexamic acid in 50cc normal saline in 15 minut and patients in control group recived 50cc normal saline in 15 minut.During the operation the patient's blood pressure is taken every 15 minutes.At the end of surgery all patients reversed and transfered to recovery.In this study we expect decreasing intraoperative bleeding in case group.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012111411455N1**

Registration date: **2013-03-17, 1391/12/27**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-03-17, 1391/12/27

Registrant information

Name

Hamidreza Deylamani

Name of organization / entity

Ahwaz (Jondishapour) University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Ahwaz (Jondishapour) University of Medical Sciences

Expected recruitment start date

2012-05-21, 1391/03/01

Expected recruitment end date

2012-12-20, 1391/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Tranexamic Acid in decreasing of intraoperative bleeding and need for deliberate hypotension in patients undergoing Functional Endoscopic Sinus Surgery.

Public title

The effect of Tranexamic Acid in decreasing of bleeding in patients undergoing Functional Endoscopic Sinus Surgery.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:16_40 years olds ASA class1 with crhonic sinusitis canditate for surgery. Exclusion

criteria: Pregnancy ; anticoagulant therapy at recent 3 months ; patients with coagulopathy.

Age

From **16 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **66**

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

Ahvaz (Jondishapour) University of Medical Sciences

Street address

Golestan

City

Ahvaz

Postal code

Approval date

2012-06-30, 1391/04/10

Ethics committee reference number

Eth-528

Health conditions studied

1

Description of health condition studied

Bleeding

ICD-10 code

T81.0

ICD-10 code description

Haemorrhage and haematoma complicating a procedure, not elsewhere classified

Primary outcomes

1

Description

Intraoperative bleeding

Timepoint

During the surgery

Method of measurement

Number of gases and soaked blood into the suction by milli liter

Secondary outcomes

1

Description

Intraoperative blood pressure

Timepoint

Every 15 minute

Method of measurement

Automated sphygmomanometer by mmhg

Intervention groups

1

Description

In intervention group 33 patients 10 mg/kg tranexamic acid in 50 cc normal saline infuse within 15 minute .

Category

Treatment - Drugs

2

Description

In control group 33 patients 50cc normal saline infuse within 15 minute.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Dr Hamidreza Deylmani

Street address

Azadegan Avenue

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz (Jondishapour) University of Medical Sciences

Full name of responsible person

Mostafa Fegghi.MD

Street address

Golestan

City

Ahvaz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Ahvaz (Jondishapour) 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**

Imam Khomini hospital

Full name of responsible person

Hamidreza Deylamani

Position

Resident of anesthesiology

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Imam Khomini Hospital

Full name of responsible person

Ali Ghomeishi.MD

Position

Assistant Professor of Department of Anesthesiology

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Web page address**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*