

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Effect of local tranexamic acid plus phenylephrine versus phenylephrine alone on reduction of bleeding and improvement of surgical field during functional endoscopic sinus surgery in patients with chronic rhinosinusitis: a double blinded randomized controlled trial

Protocol summary

Summary

Objectives: To assess the effect of local tranexamic acid on reduction of bleeding and improvement of surgical field during functional endoscopic sinus surgery in patients with chronic rhinosinusitis

Design: Double blinded randomized controlled trial

Setting and conduct: The eligible patients with chronic rhinosinusitis who will refer to ENT clinic of Besat hospital in 2013

Participants including major eligibility criteria as follows:

Inclusion criteria: (a) patients with chronic rhinosinusitis with or without polyposis; (b) age of 18 to 60 years; (c) hemoglobin >10 mg/dl; (d) normal CT, BT, INR, PT, PTT.

Exclusion criteria: (a) having hemorrhagic abnormality such as hemophilia; (b) thrombosis; (c) acute or chronic renal failure; (d) using heparin during 48 hours before surgery; (e) using aspirin during three days before surgery; (f) allergy to tranexamic acid; (g) cirrhosis; (h) chronic diseases such as hypertension, diabetes, and heart failure; (i) pregnancy; (j) color blind; (k) having cardiac stent; (l) having nasal tumor.

Intervention: 30 patients will receive three pads impregnated with tranexamic acid 5% and phenylephrine 0.5% for 10 minutes in each nasal cavity before surgery.

Control: 30 patients will receive three pads impregnated only with phenylephrine 0.5% for 10 minutes in each nasal cavity before surgery

Main outcome including: Primary outcomes: (a) quality of surgical field at 15, 30, and 45 minutes after surgery using Boezaart grading with 1-5 scores; (b) bleeding at 15, 30, and 45 minutes after surgery using blood accumulated in the suction chamber after reducing the amount of serum used for washing and measurement of nasopharyngeal pack weight and converting the blood weight into ml.

Secondary outcomes: measurement of (a) nausea; (b) vomiting; (c) and impaired color vision 24 hours after surgery and three days later.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201212139014N15**

Registration date: **2013-08-11, 1392/05/20**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-08-11, 1392/05/20

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor of Research the Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2013-06-22, 1392/04/01

Expected recruitment end date

2013-12-22, 1392/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of local tranexamic acid plus phenylephrine versus phenylephrine alone on reduction of bleeding and improvement of surgical field during functional endoscopic sinus surgery in patients with chronic rhinosinusitis: a double blinded randomized controlled trial

Public title

Effect of local tranexamic acid plus phenylephrine versus phenylephrine on reduction of bleeding and improvement of surgical field during functional endoscopic sinus surgery in patients with chronic rhinosinusitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: (a) patients with chronic rhinosinusitis with or without polyposis; (b) age of 18 to 60 years; (c) hemoglobin >10 mg/dl; (d) normal CT, BT, INR, PT, PTT. Exclusion criteria: (a) having hemorrhagic abnormality such as hemophilia; (b) thrombosis; (c) acute or chronic renal failure; (d) using heparin during 48 hours before surgery; (e) using aspirin during three days before surgery; (f) allergy to tranexamic acid; (g) cirrhosis; (h) chronic diseases such as hypertension, diabetes, and heart failure; (i) pregnancy; (j) color blind; (k) having cardiac stent; (l) having nasal tumor.

AgeFrom **18 years** old to **60 years** old**Gender**

Both

Phase

2

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**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethic Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor of Research the Technology,
Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Postal code

6517838695

Approval date

2013-04-09, 1392/01/20

Ethics committee reference number

D/P/9/35/16

Health conditions studied**1****Description of health condition studied**

chronic rhinosinusitis

ICD-10 code

J32

ICD-10 code description

Chronic sinusitis

Primary outcomes**1****Description**

Quality of surgical field

Timepoint

15, 30 and 45 minutes after surgery

Method of measurement

using Boezaart grading with 1-5 scores

2**Description**

Bleeding

Timepoint

0.5 and one hour after surgery

Method of measurement

using blood accumulated in the suction chamber after reducing the amount of serum used for washing and measurement of nasopharyngeal pack weight and converting the blood weight into ml.

Secondary outcomes**1****Description**

Nausea

Timepoint

24 hours after surgery and three days later

Method of measurement

questionnaire

2

Description

Vomiting

Timepoint

24 hours after surgery and three days later

Method of measurement

questionnaire

3

Description

Impaired color vision

Timepoint

24 hours after surgery and three days later

Method of measurement

questionnaire

Intervention groups

1

Description

30 patients will receive three pads impregnated with tranexamic acid 5% and phenylephrine 0.5% for 10 minutes in each nasal cavity before surgery

Category

Treatment - Drugs

2

Description

30 patients will receive three pads impregnated only with phenylephrine 0.5% for 10 minutes in each nasal cavity before surgery

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat hospital

Full name of responsible person

Dr Javaneh Jahanshahi

Street address

Besat Hospital, Imam Hossein Square

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Research the Technology,
Hamadan University of Medical Sciences

Full name of responsible person

Dr Heidar Tavilani

Street address

Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

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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 the Technology, Hamadan
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

Besat Hospital

Full name of responsible person

Dr Sara Pazira

Position

Resident of ENT

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

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