Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effect of local tranexamic acid plus phenylephrine versus phenylephrine alone on reduction of bleeding and improvement of surgical filed 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 filed 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 with1-5 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

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Name of organization / entity

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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 filed 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 filed 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.
Age
From **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 with1-5 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
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 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
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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