Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The Effect of Topical Tranexamic Acid on Bleeding Reduction during Functional Endoscopic Sinus Surgery in choronic rhinosinousitis patient

Protocol summary

Study aim

1.Investigating the condition of bleeding surgery, 2-Investigating the condition of the quality of surgical field

Design

Clinical practice with a control group, community based and pragmatic, double-blind, randomized

Settings and conduct

The present study is a double-blind clinical trial on 56 patients with chronic rhinosinusitis requiring sinus endoscopic surgery which will be held in Bushehr's Hospital. Blindness will take place by random allocation by an operating room technician. For random allocation of individuals a gender-based minimization method is going to use in form of balanced blocks.the surgeon and the person assessing will get full blindness on the study , only the nurse who is supposed to perform mesh placing will be fully informed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with chronic rhinosinusitis that did not respond to drug therapy; age between 18 to 60 years old; hemoglobin above 10g/dl; the value of Bleeding time (BT), Prothrombin time (PT), Partial thromboplastin time (PTT), International normalized Ratio (INR) should be normal. Non inclusion criteria: cardiovascular disorder; taking anticoagulant drug; Inherited anticoagulant drug; Allergy to drugs; renal failure; hematuria; cirrhosis; choronic disease such as diabetes and hypertension; pregnancy; nasal tumor; color blindness.

Intervention groups

Intervention group: a mesh soaked in a mixture of phenylephrine 0.05 %vol. and transamic acid at the dose of 15 mg/kg for 10 minutes will be placed in the nose. Control group: a mesh soaked in a phenylephrine will be used.

Main outcome variables

Bleeding during surgery, quality of surgical field

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180730040640N1**
Registration date: **2018-09-30, 1397/07/08**
Registration timing: **registered_while_recruiting**

Last update: **2018-09-30, 1397/07/08**
Update count: **0**

Registration date

2018-09-30, 1397/07/08

Registrant information

Name

Reza mazarei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 77 3484 3924

Email address

r.mazarei@bpums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2019-04-21, 1398/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Topical Tranexamic Acid on Bleeding Reduction during Functional Endoscopic Sinus Surgery in choronic rhinosinousitis patient

Public title
The Effect of Topical Tranexamic Acid in endoscopic sinus surgery
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with chronic rhinosinusitis that don't not respond to drug therapy and require sinus surgery The age of the participant(s) must be between 18 and 60 years old The amount of hemoglobin of the participant should be above 10 g/dl the amount of Bleeding time (BT), Prothrombin time (PT), Partial thromboplastin time (PTT), International normalized Ratio (INR) should be normal in participants.
Exclusion criteria:
Participants with cardiovascular disorders. Participants who have coagulation disorders or who are taking anticoagulant medicines(drugs) Participants with inherited coagulation disorders such as thrombophilia. Participants with coagulation disorders history in the past. Participants who have a history (record) of allergy to any drug(s) in the past. Participants who have been suffering from renal deficiency in the past. Participants with cirrhosis. Participants with chronic diseases, such as diabetes and hypertension. Participants who are pregnant. participants with malignant nasal tumor. Color blindness
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Investigator
- Data analyser

Sample size
Target sample size: **56**
Randomization (investigator's opinion)
Randomized
Randomization description
For random allocation of participants (individuals), a gender-based minimization method and balanced blocks will be used.
Blinding (investigator's opinion)
Double blinded
Blinding description
The present study is a double-blind clinical trial on 56 patients with chronic rhinosinusitis requiring sinus endoscopic surgery which will be held in Bushehr’s Hospital.Blindness will take place by random allocation by an operating room technician.For random allocation of individuals a gender-based minimization method is going to use in form of balanced blocks.the surgeon and the person assessing will get full blindness on the study , only the nurse who is supposed to perform mesh placing will be fully informed.
Placebo
Not used
Assignment
Other
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics comittee of Bushehr University of Medical Sciences
Street address
Sabzabad Blvd, Salman Farsi street, Reishehr
City
Bushehr
Province
Boushehr
Postal code
7517933755
Approval date
2018-08-19, 1397/05/28
Ethics committee reference number
IR.BPUMS.REC.1397.040

Health conditions studied

1

Description of health condition studied
Bleeding control and improvement of the quality of surgical field in sinus endoscopic surgery of those who need surgery that did not respond to drug therapy.
ICD-10 code
J32.9
ICD-10 code description
Chronic sinusitis, unspecified

Primary outcomes

1

Description
bleeding during surgery
Timepoint
At 15th, 30th and 45th minute after intervention
Method of measurement
The Boezaart measuring scale

2

Description
Surgeon's satisfaction with quality of surgical field.
Timepoint
At 15th, 30th and 45th minute after intervention
Method of measurement

Likert scale plan for satisfaction

Secondary outcomes

1

Description
blood pressure
Timepoint
every 15 minutes after start of surgery
Method of measurement
heart monitoring

2

Description
bleeding volume
Timepoint
every 15 minutes after start of surgery
Method of measurement
suction device

3

Description
pulse rate
Timepoint
every 15 minutes after start of surgery
Method of measurement
heart monitoring

Intervention groups

1

Description
Intervention group: a group of 56 patients with chronic rhinosinusitis, requiring sinus endoscopic surgery was obtained. For preoperation patient , a mesh soaked in a mixture of phenylephrine 0.05 %vol. and transamic acid at a dose of 15 mg / kg for 10 minutes will be placed in the nose(nasal cavity) of the patient by an operating room technician, then it will get extracted and operation(procedure) will begin. Bleeding rate will measure according to the Boezaart grade scale and the surgeon's satisfaction is going to measure based on the Likert scale.
Category
Treatment - Surgery

2

Description
Control group: This group is consist of 56 patients with chronic rhinosinusitis, requiring surgical endoscopy of the sinus. In this group, a mesh soaked in a solution of 0.05%vol. of phenylephrine for 10 minutes will be placed in the nose(nasal cavity) of the patient by an operating room technician, then the mesh will get extracted and operation(procedure) begins. Bleeding rate would measure according to the Boezaart grade scale and the surgeon's satisfaction will measure based on the Likert scale.Clinical practice with a control group, community based and pragmatic, double-blind, randomized
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Khalije Fars hospital
Full name of responsible person
Atefehe Sfandiari
Street address
Taleghani Avenue
City
Boushehr
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Boushehr
Postal code
7517933755
Phone
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Fax
+98 77 3345 5390
Email
atefehesfandiari88@gmail.com
Web page address
http://www.mpgh.bpums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Boushehr University of Medical Sciences
Full name of responsible person
Gholamreza Khamisipour
Street address
Sabzabad Blvd, Salman Farsi street, Reishehr
City
Boushehr
Province
Boushehr
Postal code
7518759577
Phone
+98 77 3345 0187
Fax
+98 77 3345 0178
Email
Khamisipour@bpums.ac.ir
Web page address
http://www.bpums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source

Boushehr University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Boushehr University of Medical Sciences

Full name of responsible person

Allahkaram Akhlaghi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Ear, Nose, and Throat

Street address

Units 16, Block 1, Fatemeh Zahra pension, Moallem square, Siraf Ave

City

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Province

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Postal code

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Phone

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Email

Akhlaghidr@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Boushehr University of Medical Sciences

Full name of responsible person

Allahkaram Akhlaghi

Position

Allahkaram akhlaghi

Latest degree

Specialist

Other areas of specialty/work

Ear, Nose, and Throat

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Akhlaghidr@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Boushehr University of Medical Sciences

Full name of responsible person

Allahkaram Akhlaghi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Ear, Nose, and Throat

Street address

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Email

Akhlaghidr@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

No.There is not a plan to make this available

When the data will become available and for how long

No.There is not a plan to make this available

To whom data/document is available

No.There is not a plan to make this available

Under which criteria data/document could be used

No.There is not a plan to make this available

From where data/document is obtainable

No.There is not a plan to make this available

What processes are involved for a request to access data/document

No.There is not a plan to make this available

Comments