

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

The Effect of Topical Tranexamic Acid on Bleeding Reduction during Functional Endoscopic Sinus Surgery in chronic rhinosinusitis 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; chronic 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 tranexamic acid at the dose of 15 mg/kg for 10 minutes will be placed in the nose. Control group: a mesh soaked in 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 chronic rhinosinusitis 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 committee 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

Province

Boushehr

Postal code

7517933755

Phone

+98 77 3345 5374

Fax

+98 77 3345 5390

Email

atefehsfandiari88@gmail.com

Web page address

<http://www.mpgb.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
Boushehr
Province
Boushehr
Postal code
7517933755
Phone
+98 77 3484 3924
Fax
+98 77 3345 5390
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
Street address
Units 16, Block 1, Fatemeh Zahra pension, Moallem square, Siraf Ave
City
Boushehr
Province

Boushehr
Postal code
7517933755
Phone
+98 77 3484 3924
Fax
+98 77 3345 5390
Email
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
Units 16, Block 1, Fatemeh Zahra pension, Moallem square, Siraf Ave
City
Boushehr
Province
Boushehr
Postal code
7517933755
Phone
+98 77 3484 3924
Fax
+98 77 3345 5390
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