

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 2026

### The effect of labetolol on reducing bleeding during and after functional endoscopic sinus surgery(FESS) in patients scheduled for surgery

#### Protocol summary

##### Summary

The aim of this trial is to assess the effect of preoperative labetolol on the amount of bleeding during functional endoscopic sinus surgery(FESS). After signing written informed consent by parents, 32 patients, aged 20-60 years, with no contraindication for using study drugs, and scheduled for FESS, will be enrolled in this double-blind randomized controlled trial and randomly allocated into two groups. Patients with any positive history for coagulation disorders, cerebral/cardiac ischemia, liver, kidney, lung, heart disease or endocrinopathies or those who need to receive different anesthetic regimen will be excluded. The patients in the intervention group will receive labetolol infusion, 1 mg/h after anesthesia induction. The anesthetic regimen is similar for both groups. Amount of bleeding and surgeon's satisfaction on surgical view will be recorded and compared between groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201511295225N6**

Registration date: **2015-12-25, 1394/10/04**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2015-12-25, 1394/10/04

##### Registrant information

###### Name

Seyed mohammad Mireskandari

###### Name of organization / entity

Tehran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

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###### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

Tehran University of Medical Sciences

##### Expected recruitment start date

2016-01-20, 1394/10/30

##### Expected recruitment end date

2016-09-20, 1395/06/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of labetolol on reducing bleeding during and after functional endoscopic sinus surgery(FESS) in patients scheduled for surgery

##### Public title

The effect of labetolol on reducing bleeding during and after functional endoscopic sinus surgery(FESS)

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion criteria: informed consent of patients, age between 20 and 60 years old, ASA class I & II, no contraindication for using study drugs, scheduled for functional endoscopic sinus surgery (FESS) Exclusion criteria: need for a different anesthetic regimen, any positive history for coagulation disorders, cerebral/cardiac ischemia, liver, kidney, lung, heart disease or endocrinopathies

##### Age

From **20 years** old to **60 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **32**

**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**

Ethics Committee of Tehran University of Medical Sciences

**Street address**

Imam Khomeini Hospital Complex, Keashavrz Blvd, Tehran

**City**

Tehran

**Postal code**

**Approval date**

2015-11-10, 1394/08/19

**Ethics committee reference number**

IR.TUMS.REC.1394.1139

**Health conditions studied**

1

**Description of health condition studied**

Chronic sinusitis

**ICD-10 code**

J32

**ICD-10 code description**

Abscess empyema infection suppuration (chronic) of sinus (accessory)(nasal)

**Primary outcomes**

1

**Description**

Bleeding

**Timepoint**

Amount of bleeding during surgery

**Method of measurement**

Checking the amount of blood in suction container at the end of surgery

**Secondary outcomes**

empty

**Intervention groups**

1

**Description**

Infusion of Labetolol 1mg/h

**Category**

Prevention

2

**Description**

10ml Normal Saline

**Category**

Placebo

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Valiasr Hospital

**Full name of responsible person**

Dr Seyed Mohammad Mireskandari

**Street address**

Valiasr Hospital, Imam Khomeini Hospital Complex, Keshavarz Blvd., Tehran

**City**

Tehran

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Vice chancellor for research, Tehran University of Medical Science

**Full name of responsible person**

Dr. Masoud Yoonesian

**Street address**

Central department of Tehran University of Medical Sciences, Intersection of Keshavarz Blvd. and Qods St.

**City**

Tehran

**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, Tehran University of Medical Science

**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**

Valiasr Hospital

**Full name of responsible person**

Dr Seyed Mohammad Mireskandari

**Position**

Anesthesiologist

**Other areas of specialty/work**

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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*