

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)

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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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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