

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Comparison of the effect of magnesium sulfate versus Dexmedetomidine on the quality of surgical filed in patients candidate for endoscopic sinus surgery: a triple blind randomized clinical trial

Protocol summary

Summary

Objectives: To assess the effect of magnesium sulfate versus Dexmedetomidine on the quality of surgical filed in patients candidate for endoscopic sinus surgery
Design: a triple blind randomized clinical trial. Setting and conduct: The eligible patients candidate for endoscopic sinus surgery and will refer to Besat Hospital during the study period will be enrolled into the trial.
Inclusion criteria: Patients candidate for endoscopic sinus surgery; age of 18 to 60 years. Exclusion criteria: Obesity with BMI index equal to or greater than 30; renal, liver, hematological, neuromuscular or hemorrhagic disorders; diabetes; using calcium blocker or NSAIDS. Intervention group 1: Magnesium sulfate infusion 50 mg/kg/ min for 10 min and then 15 mg/kg/h to the end of surgery. Intervention group 2: Dexmedetomidine infusion 1 micg/kg/ min for 10 min and then 0.5 micg/kg/h to the end of surgery. Primary outcome: Measuring bleeding at 1, 5, 15, 30 and 60 minutes after starting infusion using suction. Randomization: The patients will be randomly assigned to intervention and control groups using block randomization. Blinding: Patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. The analyzer will be unaware of the type of interventions. Therefore, the trial will be run as triple blind.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201702239014N145**

Registration date: **2017-03-04, 1395/12/14**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-03-04, 1395/12/14

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2017-03-10, 1395/12/20

Expected recruitment end date

2017-09-22, 1396/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of magnesium sulfate versus Dexmedetomidine on the quality of surgical filed in patients candidate for endoscopic sinus surgery: a triple blind randomized clinical trial

Public title

Comparison of the effect of magnesium sulfate versus Dexmedetomidine on the quality of surgical filed in patients candidate for endoscopic sinus surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients candidate for endoscopic sinus surgery; age of 18 to 60 years. Exclusion criteria: Obesity with BMI index equal to or greater than 30; renal, liver, hematological, neuromuscular or hemorrhagic disorders; diabetes; using calcium blocker or NSAIDS.

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)

Triple blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomization: The patients will be randomly assigned to intervention and control groups using block randomization. Blinding: Patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. The analyzer will be unaware of the type of interventions. Therefore, the trial will be run as triple blind.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research the Technology,
Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City

Hamadan

Postal code

6517838695

Approval date

2015-06-20, 1394/03/30

Ethics committee reference number

IR.UMSHA.REC.1394.169

Health conditions studied

1

Description of health condition studied

candidate for endoscopic sinus surgery

ICD-10 code

Y60.4

ICD-10 code description

During endoscopic examination

Primary outcomes

1

Description

Measuring bleeding

Timepoint

at 1, 5, 15, 30 and 60 minutes after starting infusion

Method of measurement

using suction

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Magnesium sulfate infusion 50 mg/kg/ min for 10 min and then 15 mg/kg/h to the end of surgery.

Category

Treatment - Drugs

2

Description

Intervention group 2: Dexmedetomidine infusion 1 micg/kg/ min for 10 min and then 0.5 micg/kg/h to the end of surgery.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital

Full name of responsible person

Dr Mahdi Shahabi Nejad

Street address

Besat Hospital, Shahed 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 Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid
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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

Full name of responsible person

Dr Mahdi Shahabi Nejad

Position

Resident of Anesthesiology

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Person responsible for updating data

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Full name of responsible person

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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