

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

Effect of intravenous infusion of dexmedetomidine with magnesium sulfate on control of bleeding and surgeon satisfaction during tympanoplasty surgery: a double-blind randomized clinical trial

Protocol summary

Study aim

To assess the effect of intravenous infusion of dexmedetomidine with magnesium sulfate on control of bleeding and surgeon satisfaction during tympanoplasty surgery

Design

This is a double-blind randomized clinical trial with comparison group, phase III, in which 40 eligible patients will be randomly assigned through the block randomization to the intervention groups

Settings and conduct

This study will be performed in the Besat Hospital in Hamadan city on 40 candidates for tympanoplasty surgery. The patients will be randomly assigned to the intervention groups through the block randomization. This trial will be double-blinded so that neither the patients nor the examiner will be aware of the type of intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18 to 61 years Candidate patients for tympanoplasty Exclusion criteria: Pregnancy Coagulation disorders Acute or chronic renal failure Liver failure Neuromuscular diseases Cardiovascular diseases

Intervention groups

Intervention group 1: Intravenous infusion of dexmedetomidine at a dose of 1 µg/kg within 15 minutes
Intervention group 2: Intravenous infusion of magnesium sulfate at a dose of 40 mg/kg within 15 minutes

Main outcome variables

Primary outcome: Intraoperative bleeding volume, surgeon satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N427**

Registration date: **2022-05-18, 1401/02/28**

Registration timing: **prospective**

Last update: **2022-05-18, 1401/02/28**

Update count: **0**

Registration date

2022-05-18, 1401/02/28

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 81 1838 0090

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-05, 1401/03/15

Expected recruitment end date

2023-03-06, 1401/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of intravenous infusion of dexmedetomidine with

magnesium sulfate on control of bleeding and surgeon satisfaction during tympanoplasty surgery: a double-blind randomized clinical trial

Public title

Effect of intravenous infusion of dexmedetomidine with magnesium sulfate on control of bleeding and surgeon satisfaction during tympanoplasty surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 to 61 years Candidate patients for tympanoplasty

Exclusion criteria:

Pregnancy Coagulation disorders Acute or chronic renal failure Liver failure Neuromuscular diseases Cardiovascular diseases

Age

From **18 years** old to **61 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention 1 and on the other two sheets the name of the intervention 2. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.

Blinding (investigator's opinion)

Double blinded

Blinding description

The shape of the medications will be perfectly the same. Therefore, patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Thus, the trial will be run as double-blind.

Placebo

Not used

Assignment

Parallel

Other design features

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 and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2022-05-07, 1401/02/17

Ethics committee reference number

IR.UMSHA.REC.1401.129

Health conditions studied

1

Description of health condition studied

Perforation of tympanic membrane

ICD-10 code

H72

ICD-10 code description

Perforation of tympanic membrane

Primary outcomes

1

Description

Intraoperative bleeding volume

Timepoint

After surgery

Method of measurement

By measuring the volume of the suction bottle (after deducting the volume of normal saline used)

2

Description

Surgeon satisfaction

Timepoint

After surgery

Method of measurement

Using 5-point Likert scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Intravenous infusion of dexmedetomidine at a dose of 1 µg/kg within 15 minutes

Category

Treatment - Drugs

2

Description

Intervention group 2: Intravenous infusion of magnesium sulfate at a dose of 40 mg/kg within 15 minutes

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital in Hamadan city

Full name of responsible person

Mohammad Khajavi

Street address

Besat Hospital, Shahed Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Reza Shokoohi

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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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Mohammad Khajavi

Position

Medical Student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

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ENT Specialist

Latest degree

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Other areas of specialty/work

Ear, Nose, and Throat

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available