Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 not 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

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Jalal Poorolajal

Name of organization / entity
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Iran (Islamic Republic of)

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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

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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
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Sponsors / Funding sources

1

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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
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Person responsible for updating data

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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