Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Aug 2026

The comparative Evaluation of Efficacy of intravenous magnesium sulphate with lidocaine 2% in preventing laryngospasm and postoperative pain after tonsilectomy: Double blind clinlcal trial

Protocol summary

Study aim
Evaluation of Efficacy of intravenous magnesium sulphate with lidocaine 2% in preventing laryngospasm and postoperative pain after tonsilectomy

Design
62 children aged 3-14 years admitted for adeno tonsillectomy randomly assigned into a randomized, double blind clinical trial with 4 blocks, were divided into one of two groups of intravenous injection of 2% lidocaine or magnesium sulfate.

Settings and conduct
In this double-blind randomized clinical trial children 3-14 years old, candidates for adenotonsillectomy will be randomly assigned to either 2% lidocaine or magnesium sulfate. Following anesthesia induction and intubation, patients will receive either lidocaine or magnesium sulfate intravenously, that prepared by an anesthetic nurse of similar size and volume.The patient and anesthesiologist (evaluator) are not aware of the type of medication prescribed. Then patients will be examined for laryngospasm after tracheal extubation.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Age 3-14 years old with ASA Class 1 & 2; Candidates for adenotonsillectomy; Parental consent to participate in the project. Exclusion Criteria: Heart, pulmonary and renal disease; Recent infection of the upper respiratory tract and fever; A history of allergies to magnesium sulfate, lidocaine; Probability of intubation difficulty; Corticosteroid intake; Arrhythmias and heart blocks; A history of myasthenia gravis

Intervention groups
Intervention group 1: Children 3-14 years of age candidates for adenotonsillectomy will receive 15 mg / kg magnesium sulfate in a total volume of 15 ml two minutes after intubation. Intervention group 2: Children 3-14 years of age candidate for adenotonsillectomy will receive lidocaine 1mg / kg in a total volume of 15ml two minutes after intubation.

Main outcome variables
Laryngospasm

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120915010841N22**
Registration date: **2020-01-24, 1398/11/04**
Registration timing: **registered_while_recruiting**

Last update: **2020-01-24, 1398/11/04**
Update count: **0**

Registration date
2020-01-24, 1398/11/04

Registrant information

Name
Nahid Manuchehrian

Name of organization / entity
Hamedan University of Medical Sciences

Country
Iran (Islamic Republic of)

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manouchehrian@umsha.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-11-01, 1398/08/10

Expected recruitment end date
2020-10-31, 1399/08/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparative Evaluation of Efficacy of intravenous magnesium sulphate with lidocaine 2% in preventing laryngospasm and postoperative pain after tonsilectomy: Double blind clinlcal trial

Public title

Evaluation of Efficacy of intravenous magnesium sulphate with lidocaine 2% in preventing laryngospasm and postoperative pain after tonsilectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 3-14 years old with ASA Class 1 & 2 Candidate for elective adenotonsillectomy Parental consent to participate in the project

Exclusion criteria:

Heart, pulmonary and renal disease Recent infection of the upper respiratory tract and fever A history of allergies to magnesium sulfate, lidocaine Probability of intubation difficult Corticosteroid intake Arrhythmias and heart blocks A history of myasthenia gravis

Age

From **3 years** old to **14 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **62**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, block randomization as a four-block design will be used. In this way, according to the sample size,16 blocks of four are identified, and in each of these four blocks, two person of each group will be written in the form of letters A (Magnesium sulfate) or B(Lidocaine). This means that two letters A and two letters B will be written in each block, although the order of the writing of the four letters A and B will be different in each block. The random numbers table will then be used to determine the order of block selection.

Blinding (investigator's opinion)

Double blinded

Blinding description

For each group A or B, one of two drugs (magnesium sulfate or lidocaine) will be prescribed after spinal anesthesia. For blinding of patients and the researcher, the syringes for both groups will be in similar size and shape with A or B labels on them. Medications will be prepared and injected by the anesthesiologist. Since the drugs will be prescribed and administered by the anesthesiologist. The assistant who will measure and record the outcome of the study will not be aware of the type of medication prescribed.

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

Mahdieh Street

City

Hamadan

Province

Hamadan

Postal code

6517838678

Approval date

2019-06-15, 1398/03/25

Ethics committee reference number

IR.UMSHA.REC.1398.231

Health conditions studied

1

Description of health condition studied

laryngospasm and complications after tonsilectomy

ICD-10 code

J38.5

ICD-10 code description

Laryngeal spasm

Primary outcomes

1

Description

laryngospasm

Timepoint

1, 5, 10 and 15 minutes after extubation

Method of measurement

Observation

Secondary outcomes

1

Description
Nausea & vomiting
Timepoint
After surgery
Method of measurement
Observation

2

Description
Systolic and Diastolic Blood Pressure
Timepoint
Every two minutes for 10 minutes and then every 10 minutes to 60 minute
Method of measurement
Non-invasive automatic barometric device

3

Description
Heart Rate
Timepoint
Every two minutes for 10 minutes and then every 10 minutes to 60 minute
Method of measurement
Non-invasive automatic barometric device

4

Description
sedation
Timepoint
We record ramsy sedation score in 24 hours after surgery.
Method of measurement
Ramsy sedation score

Intervention groups

1

Description
Intervention group: Children 3-14 years of age candidate for adenotonsillectomy will receive 15 mg / kg magnesium sulfate in a total volume of 15 ml two minutes after intubation.
Category
Treatment - Drugs

2

Description
Intervention group: Children 3-14 years of age candidate for adenotonsillectomy will receive lidocaine 1mg / kg in a total volume of 15ml two minutes after intubation.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Besat Hospital
Full name of responsible person
Nahid Manouchehrian, Anesthesiologist, Assistant Professor of Hamadan University Of Medical Sciences
Street address
Besat Hospital in Hamadan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Dr. Saeed Bashirian
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6517838678
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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
Nahid Manouchehrian

Position
Associate professor of Hamadan University of Medical Sciences

Latest degree
Subspecialist

Other areas of specialty/work
Anesthesiology

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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