

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 tonsillectomy: Double blind clinical trial

Protocol summary

Study aim

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

Design

62 children aged 3-14 years admitted for adenotonsillectomy 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 Manouchehrian

Name of organization / entity

Hamedan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1827 7012

Email address

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 clinical 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 ramsey sedation score in 24 hours after surgery.

Method of measurement

Ramsey 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

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vc_research@umsha.ac.ir

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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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