

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

study and compare two different doses of magnesium sulfate in decreasing pain and agitation of children after tonsillectomy

Protocol summary

Study aim

Study and compare two different doses of magnesium sulfate in decreasing pain and agitation of children after tonsillectomy

Design

It is a double-blinded randomized clinical trial sampling will be done among children referred for tonsillectomy aged between 3 to 15 years old after receiving written consent and explaining the purpose of the study. patients will be randomly divided into 3 groups(each group 40 patients) using random allocation software consisting of one control group and two intervention groups

Settings and conduct

pain after tonsillectomy is a big problem because it affects the time of recovery. this study is a double-blinded randomized clinical trial that takes place in the fall of 1400 in Vali-Asr hospital. the control group receives the placebo. The first and second intervention groups receive 2 different doses of magnesium sulfate respectively. after extubation, measurement of pain and agitation will be performed by uninformed personnel in 5,10,15,30 minutes and then after 1,2,6 hours based on Ricker-sedation-agitation score and FLACC score. preparation of medication and will be performed and labeled as A,B,C by researchers and will be given to OR person who has no idea about labels meaning. As above,Statistical analyzer analyzes the data uniformly.

Participants/Inclusion and exclusion criteria

Inclusion criteria: consent of patient and parents Aged between 3 to 15 need to do tonsillectomy ASA class I II II
Exclusion criteria: Unwillingness to participate in the study ASA class IV anatomical abnormalities in airway reoperation due to bleeding difficult intubation History of cardiology, renal, respiratory diseases and MG

Intervention groups

This study includes 3 groups. first one is the control group. control group receives placebo. intervention groups receive two different doses of magnesium sulfate.

Main outcome variables

decrease in pain post-tonsillectomy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211121053130N1**

Registration date: **2021-12-11, 1400/09/20**

Registration timing: **registered_while_recruiting**

Last update: **2021-12-11, 1400/09/20**

Update count: **0**

Registration date

2021-12-11, 1400/09/20

Registrant information

Name

Mohammad reza Maleklotiei

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 71 3648 3878

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rezamaleklotiei@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-11, 1400/09/20

Expected recruitment end date

2021-12-28, 1400/10/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

study and compare two different doses of magnesium sulfate in decreasing pain and agitation of children after tonsillectomy

Public title

effect of magnesium sulfate on pain and agitation after tonsillectomy

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

consent of patient and parents ASA class I II II need to do tonsillectomy ASA class I II II

Exclusion criteria:

Unwillingness to participate in study ASA class IV anatomical abnormalities in airway reoperation due to bleeding difficult intubation History of cardiology,renal,respiratory diseases History of MG

Age

From **3 years** old to **15 years** old

Gender

Both

Phase

3

Groups that have been masked

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

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

After generating random block sequences by Random Allocation Software version 1.0.0, the sequences in each block will be placed in numbered envelopes. for each group of patients, we randomly select one of the blocks, the sequences in each block will be used to assign individuals to one of the study groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

preparation of medication and placebo will be performed and labeled as A,B,C by researchers and will be given to OR personel who has no idea about labels meaning. researchers have no role in giving the medication and measuring the outcome. As above,Statistical analyzer will analyze the data without the knowledge that each group receive which medication.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of fasa University of Medical Sciences

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ebne sina square fasa fars

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fasa

Province

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Postal code

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Approval date

2021-11-21, 1400/08/30

Ethics committee reference number

IR.FUMS.REC.1400.090

Health conditions studied**1****Description of health condition studied**

pain and agitation after tonsillectomy in children

ICD-10 code

J35.1

ICD-10 code description

Hypertrophy of tonsils

Primary outcomes**1****Description**

pain

Timepoint

5 minutes after extubation/10 minutes after extubation/15 minutes after extubation/30 minutes after extubation/1hour after extubation/2 hour after extubation/6 hour after extubation/

Method of measurement

FLACC score for pain

Secondary outcomes**1****Description**

agitation

Timepoint

5 minutes after extubation/10 minutes after extubation/15 minutes after extubation/30 minutes after extubation/1hour after extubation/2 hour after extubation/6 hour after extubation/

Method of measurement

Intervention groups

1

Description

Control group: anesthesia induction will be done by administration of midazolam 0.5-1 mg/kg , Atra 0.4-0.6 mg/kg , STP 5-7 mg/kg and fentanyl 2mcg/kg by anesthesiologist.first group as control group will receive no further medication but placebo with same administration method of magnesium sulfate.

Category

Placebo

2

Description

first Intervention group: anesthesia induction will be done by administration of midazolam 0.5-1 mg/kg , Atra 0.4-0.6 mg/kg , STP 5-7 mg/kg and fentanyl 2mcg/kg by anesthesiologist.then the will receive 30 mg/kg mg sulfate as loading dose followed by 10mg/kg/hr for 1 hour as maintenance dose

Category

Treatment - Drugs

3

Description

second Intervention group: anesthesia induction will be done by administration of midazolam 0.5-1 mg/kg , Atra 0.4-0.6 mg/kg , STP 5-7 mg/kg and fentanyl 2mcg/kg by anesthesiologist.then the will receive 40 mg/kg mg sulfate as loading dose followed by 10mg/kg/hr for 1 hour as maintenance dose

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Vali asr fasa hospital ,FASA

Full name of responsible person

Mohammad Reza Malek Motiei

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Fasa 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

Fasa University of Medical Sciences

Full name of responsible person

Mohammad Reza Malek Motiei

Position

Medical intern

Latest degree

Medical doctor

Other areas of specialty/work

Ear, Nose, and Throat

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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