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 labeld as A,B,C by researchers and will be given to OR personel who has no idea about labels meaning. As above,Statistical analyzer analyzes the data uniformedly.

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 Malekmotiei

Name of organization / entity

Country
Iran (Islamic Republic of)

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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 parentsASA 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 labeld 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

Street address
ebne sina square fasa fars

City
fasa

Province
Fars

Postal code
۸۶۶۸۸ - ۷۴۶۱۶

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

Ricker-sedation-agitation score

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 fallowed 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 fallowed 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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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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Latest degree

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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