

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jun 2026

A survey on the effects of intravenous sulfate magnesium on laryngospasm after elective Adenotonsillectomy surgery in children

Protocol summary

Summary

Laryngospasm is common after adenotonsillectomy. For laryngospasm relief various techniques are suggested. The aim of this study is the clinical effectiveness of magnesium sulfate with placebo. For this reason in a patient – observer blind randomized clinical trial 70 patients from 3 to 12 years old that scheduled for Adenotonsillectomy will select (after explaining the process of the trial and written informed consent obtained from participants) then they will receive magnesium sulfate 15mg/kg and second group will receive saline normal 0.9% with the same volume within 20 minutes. Cough and laryngospasm and oxygen saturation will be recorded after extube in 0,15 and 30 minutes in post Anesthesia care unit.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201207181138N10**

Registration date: **2012-08-16, 1391/05/26**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-08-16, 1391/05/26

Registrant information

Name

Fataneh Bakhshi

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 1223 8307

Email address

entrc@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Guilan University of Medical Sciences, Research Vice

Expected recruitment start date

2012-07-22, 1391/05/01

Expected recruitment end date

2012-07-22, 1391/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A survey on the effects of intravenous sulfate magnesium on laryngospasm after elective Adenotonsillectomy surgery in children

Public title

The effects of Sulfate Magnesium on Children's Laryngospasm

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: patients candidate for elective Adenotonsillectomy surgery (3 – 12yr); ASA class I, II
Exclusion criteria: Emergency surgery, re-operation, history of respiratory, cardiac, renal disease, upper respiratory tract infection, myasthenia gravis, history of difficult intubation or extubation, supra glottitis ,history of the known seasitivity to magnesium sulfate, heart block ,hypotesion.

Age

From **3 years** old to **12 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 70

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Guilan University of Medical Sciences

Street address

Siadati st.

City

Rasht

Postal code

Approval date

2012-05-14, 1391/02/25

Ethics committee reference number

671

Health conditions studied

1

Description of health condition studied

Laryngospasm

ICD-10 code

Acute lary

ICD-10 code description

oedematous

Primary outcomes

1

Description

Laryngospasm

Timepoint

minute of 0- 15- 30 & 60

Method of measurement

Oxygen Saturation

Secondary outcomes

1

Description

Cough

Timepoint

Minutes of 0- 15-30 & 60

Method of measurement

Four degree scale

Intervention groups

1

Description

Magnesium sulfate 15mg/kg in 20 minutes

Category

Treatment - Drugs

2

Description

Saline normal 0.9% with the same volume of drug

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amiralmomenin Hospital

Full name of responsible person

Street address

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Guilan University of Medical Sciences

Full name of responsible person

Susan Komaii

Street address

Siadati St.

City

Rasht

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Guilan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Guilan University of Medical Sciences

Full name of responsible person

Dr Sudabeh Haddadi

Position

Assistant Professor of Anesthesia

Other areas of specialty/work**Street address**

Amiralmomenin Hospital, 17 Shahrivar St.

City

Rasht

Postal code**Phone**

+98 13 1222 5242

Fax**Email**

so_haddadi@gums.ac.ir

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Guilan University of Medical Sciences

Full name of responsible person

Sudabeh Haddadi

Position

Assistant Professor of Anesthesia

Other areas of specialty/work**Street address**

Amiralmomenin hospital, 17 Shahrivar St.

City

Rasht

Postal code**Phone**

+98 13 1222 5242

Fax**Email**

so_haddadi@gums.ac.ir

Web page address**Person responsible for updating data****Contact****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty