

# 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.

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**Postal code****Phone**

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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**

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**City**

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**Postal code****Phone**

+98 13 1222 5242

**Fax****Email**

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**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*