

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

The effect of intravenous magnesium sulfate on intraocular pressure changes following tracheal intubation in adults in Shiraz University affiliated hospital

Protocol summary

Summary

Magnesium sulfate a cost effective and safe drug. Magnesium can act as adrenergic antagonist and inhibited the release of catecholamines. One of the most problems in the anesthesia is control of pressure responses due to laryngoscopic intubation. This study was designed to assess the effect of magnesium sulfate on pressure responses of laryngoscopic intubation in anesthesia including hypertension, tachycardia and increased in intraocular pressure (IOP). This randomized, double blind study was conducted in 180 patients ASA I that were undergoing non ocular surgery. The magnesium group A (n 90) received 30 mg/kg before induction of anesthesia and group B (n 90) received the same volume of normal saline. Intra ocular pressure, hemodynamic variables and heart rate measured in 4 stages: before induction of anesthesia (T1), just before intubation (T2), 1minute after intubation (T3), and 5 minute after intubation (T4). These revealed significant interaction effect when comparing IOP in two groups in T2 to T3; (P=0.031). There were significant differences between in the Systolic BP (p= 0.018), in the Diastolic BP (p= 0.01), in the Mean BP (p= 0.027), in two groups across levels of time. There was not an overall significant difference in the heart rate between two groups. (P= 0.524) Intravenous magnesium sulfate before induction of anesthesia reduced pressure responses of laryngoscopic intubation, and attenuated IOP in the time of before and after intubation. This attenuation is might be related to reduction in the release of catecholamine and vasodilatation of smooth muscle of systemic vessels. Keyword: magnesium sulfate, IOP.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138812013376N1**

Registration date: **2011-02-16, 1389/11/27**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-02-16, 1389/11/27

Registrant information

Name

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Name of organization / entity

Shiraz University of Medical Science

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research Affairs of Shiraz University of Medical Science , Anesthesia department

Expected recruitment start date

2007-07-23, 1386/05/01

Expected recruitment end date

2009-09-16, 1388/06/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of intravenous magnesium sulfate on intraocular pressure changes following tracheal intubation in adults in Shiraz University affiliated hospital

Public title

The effect of Magnesium sulphate on increased intraocular pressure due to general anesthesia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: 180 patients (ASA I) healthy adult, (18 to 38years old, both man and woman) that were scheduled for elective non ocular surgery (ENT and ambulatory surgery that needed tracheal intubation), were selected. exclusion criteria: The patients with specific major hepatic, renal and cardio-vascular disease as well as those known to have allergic reaction to magnesium sulphate or other drugs on basis of the history of patients, and hypermagnesemia, hypocalcemia on the basis on lab data, anuria, heart block (ECG), pregnancy, any degree of renal insufficiency, digitalised patients, positive history of glaucoma, or intra ocular hypertension, and patients who refused to participate in this study, were excluded.

Age

From **18 years** old to **38 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **180**

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

Shiraz University of Medical Science

Street address

Shiraz, Zand avenue, Central building of Shiraz
University of Medical Science

City

Shiraz

Postal code

71345 - 1978

Approval date

2008-03-16, 1386/12/26

Ethics committee reference number

3905-86

Health conditions studied

1

Description of health condition studied

Persons encountering health services for specific procedures and health care

ICD-10 code

Z40 - Z41

ICD-10 code description

Persons encountering health services for specific procedures and health care

Primary outcomes

1

Description

iop (Intra ocular pressure)

Timepoint

In 4 stage (T1:Before induction of anesthesia ,T2 :just before intubation , T3:1 minute after intubation ,T4:5 minute after intubation

Method of measurement

TONOPEN Instrument

Secondary outcomes

1

Description

Systolic BP

Timepoint

4 stages ; T1 :Before Induction of anesthesia , T2 : just before intubation ,T3 : 1 minute after intubation, T4 :5 minute after intubation

Method of measurement

NIBP monitoring

2

Description

Diastolic BP

Timepoint

4 stages ; T1 :Before Induction of anesthesia , T2 : just before intubation ,T3 : 1 minute after intubation, T4 :5 minute after intubation

Method of measurement

NIBP monitoring

3

Description

Mean Arterial Pressure

Timepoint

4 stages ; T1 :Before Induction of anesthesia , T2 : just before intubation ,T3 : 1 minute after intubation, T4 :5 minute after intubation

Method of measurement

NIBP monitoring

4

Description

Heart Rate

Timepoint

4 stages ; T1 :Before Induction of anesthesia , T2 : just before intubation ,T3 : 1 minute after intubation, T4 :5 minute after intubation

Method of measurement

EKG monitoring

Intervention groups

1

Description

administration of magnesium sulphate once 30mg/kg IV before induction of Anesthesia

Category

Prevention

2

Description

administration of normal saline once 30mg/kg IV before induction of Anesthesia

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Khalili and Dastgheib Shiraz University affiliated hospitals

Full name of responsible person

Fatemeh Karami tire shabankare

Street address

Shiraz University of medical of science,Faghihi hospital, nesthesia department

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research of Shiraz University of Medical Science,Anesthesia department

Full name of responsible person

Dr Mohammad ali sahmeddini

Street address

Shiraz university of Medical Science, central buldding,7th stairs,research and technology center

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for Research of Shiraz University of Medical Science,Anesthesia department

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

Shiraz Universityof Medical Science

Full name of responsible person

Dr Sina Ghaffari pour

Position

Assistant Professor of Anesthesiology

Other areas of specialty/work

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Position

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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