

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

An assessment on efficacy of intravenous magnesium sulphate on pain relief after abdominal hystrectomy

Protocol summary

Summary

The study is a double-blinded, experimental and clinical trial. It will be accomplished after inform consent, on 102 cases, between 35-55 years old. All patients have undergone abdominal hysterectomy under general anesthesia. Sampling will be done from January 2014 to January 2015. Cases with same inclusion criterion, will put in three different groups(1-2-3) with Random-Block method. In this respect, cases will be divided into three groups(1, 2, 3), and a pocket will be allocated to them. Patients will be received one of the pockets by one of the colleagues who do not know about contents. The groups arrange in this manner: 1)Will receive bolus Mg-sulphate(50%)(50mg/kg) during 15 minutes, before the induction. 2)Will receive 50mg/kg ,bolus of Mg-sulphate(during 15 minutes) before the induction and then 15 mg/kg/hr continuously. 3) Will receive just 100 ml of Normal saline. Injections will be performed by colleagues blindly. Monitoring should be performed with ECG, sphygmomanometer, pulse-oxymetry and nerve-stimulator. After 6 hours fasting, induction will be exerted with sodium thiopental, succinyl-choline and Fentanyl. Then maintenance should be accomplished with Isoflurane,O₂,N₂O, Atracurium and incremental doses of Fentanyl. Patients will be reversed with Neostigmine and Atropine.All cases will be monitored according to PR(pulse rate),BP(blood pressure) throughout 24 hours. Pain score will be recorded with Visual Analogue Scale(VAS), 1-6-18-24 hours after the surgery. With VAS more than 4;Pethidine with dose of 0.5 mg/kg will be recommended. The time interval between the end of surgery and the first dose of Pethidine will be accounted as Analgesic Time.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014012316325N1**

Registration date: **2014-03-06, 1392/12/15**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-03-06, 1392/12/15

Registrant information

Name

Katayoun Haryalchi

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 1322 5624

Email address

haryalchi@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Guilan University of Medical Sciences

Expected recruitment start date

2014-03-03, 1392/12/12

Expected recruitment end date

2015-01-01, 1393/10/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

An assessment on efficacy of intravenous magnesium sulphate on pain relief after abdominal hysterectomy

Public title

An assessment on intravenous magnesium sulphate on pain relief after abdominal hystrectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Age between 35-55; ASA I,II; No previous abdominal surgeries; systemic major cardiovascular diseases; musculoskeletal disorders; hepatic diseases; Calcium beta-blocker consumption; No previous renal insufficiency; nephropathy; myopathy; No allergy to Mg sulphate or other drugs; No drug abuse
Exclusion criteria: Surgeries which will lasted more than 1 hour

Age

From **35 years** old to **55 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **102**

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 Science

Street address

Vice Chancellor for Research-Guilan University of
Medical Sciences

City

Rasht

Postal code**Approval date**

2013-12-07, 1392/09/16

Ethics committee reference number

5920341308

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

Hysterectomy

ICD-10 code

N99.9

ICD-10 code description

Postprocedural disorder of genitourinary system, unspecified

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

Pain severity

Timepoint

1-6-18-24 hours

Method of measurement

Visual Analog Scale(VAS)

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

Adverse drug reaction

Timepoint

1-6-18-24 hours

Method of measurement

History

2**Description**

Pethidine consumption

Timepoint

1-6-18-24 hours

Method of measurement

Whole pethidine dose usage

Intervention groups**1****Description**

Administration of bolus Mg-sulphate (50%) (50mg/kg) during 15 minutes, before the induction.

Category

Treatment - Drugs

2**Description**

Administration of Mg-sulphate with dose of 50mg/kg (bolus) (during 15 minutes) before the induction and then 15 mg/kg/hr continuously.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Street address

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Guilan University of Medical Sciences-Rasht-Iran

Full name of responsible person

Dr. Abdolrasol Sobhani

Street address

Vice Chancellor for Research, Guilan University of Medical Sciences, Namjoo street

City

Rasht

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, Guilan University of Medical Sciences-Rasht-Iran

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. Katayoun Haryalchi

Position

Assistant Professor of Anesthesiology of Guilan University of Medical Sciences

Other areas of specialty/work

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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Guilan University of Medical Sciences

Full name of responsible person

Dr. Katayoun Haryalchi

Position

Assistant Professor of Anesthesiology of Guilan University of Medical Sciences

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Guilan University of Medical Sciences

Full name of responsible person

Seyedeh Fatemeh Dalil Heirati

Position

B.S.Midwife

Other areas of specialty/work

Street address

Reproductive Health Research Center, Alzahra hospital, Namjoo street

City

Rasht

Postal code

Phone

00

Fax

Email

Web page address

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