

# 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,O<sub>2</sub>,/N<sub>2</sub>O, 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 hysterectomy

**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**

**Street address**

Reproductive Health Research Center, Alzahra hospital, Namjo street

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## Person responsible for scientific inquiries

### Contact

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**Full name of responsible person**

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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**

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**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*