

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of Methocarbamol on postoperative pain following Inguinal Hernia surgery

#### Protocol summary

##### Summary

The purpose of this project is to better controlling of the pain after inguinal hernia surgery. One of the causes of pain after hernia surgery is muscle spasm due to surgical stimulation and we expect Methocarbamol as an anti-spasm drug can control the pain after hernia surgery. A random clinical trial study will be performed among two groups of control and intervention. It was a parallel single blind and single center (Imam Hossein Hospital, Shahroud) trial. The control group will receive the placebo and the intervention group will receive Methocarbamol. Study is the second phase of clinical trial. All people who are at the age of 15 to 55 and their weight are below 100kg will be included in the study if they're willing. People who have severe underlying disease or drug allergy will be excluded from the study. The sample size is 72. Patients will be randomly divided into two equal groups of intervention and control by dice. The intervention group will receive 500 mg intravenous Methocarbamol half an hour after surgery and then Methocarbamol 1gr tablet every 8 hrs for one week. The control group will receive normal saline 10 cc intravenously and oral placebo tablets for a week. The pain level will be assessed 1, 6, 12, 24 hrs and one week after the operation and the assessment will be based on the measurement (VAS), the Pethidine need during first 24 hrs and Ibuprofen tablets need during first week. The main outcome will be pain after inguinal hernia surgery.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017070434898N1**

Registration date: **2017-08-23, 1396/06/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-08-23, 1396/06/01

##### Registrant information

###### Name

Mahdi Karimi

###### Name of organization / entity

Shahroud University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 23 3239 5054

###### Email address

mahdi.karimi@shmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Investigator

##### Expected recruitment start date

2016-03-20, 1395/01/01

##### Expected recruitment end date

2017-08-21, 1396/05/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of Methocarbamol on postoperative pain following Inguinal Hernia surgery

##### Public title

Effect of Methocarbamol on postoperative pain following Inguinal Hernia surgery

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Age between 15 to 55 years old;  
Weight less than 100kg; Class I,II American  
Anesthesiology Association; Patient satisfaction.  
Exclusion criteria: Co-morbid severe or chronic systemic  
disease such as Asthma, Cardio-Pulmonary, Renal and  
Hepatic disease; Drug abuse in patients; Evidence of  
allergic reactions to Methocarbamol, Ibuprofen and  
Pethidine; Patient dissatisfaction.

#### Age

From **15 years** old to **55 years** old

#### Gender

Both

#### Phase

2

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **72**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Single blinded

#### Blinding description

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Shahroud University of Medical  
Sciences

##### Street address

Shahroud University of Medical Sciences, Hafte Tir  
square, Shahroud

##### City

Shahroud

##### Postal code

۳۶۱۴۷-۷۳۹۴۷

#### Approval date

2016-01-25, 1394/11/05

#### Ethics committee reference number

IRSHMUREC.1394.181

## Health conditions studied

### 1

#### Description of health condition studied

Inguinal hernia

#### ICD-10 code

K40.9

#### ICD-10 code description

Unilateral or unspecified inguinal hernia, without  
obstruction or gangrene

## Primary outcomes

### 1

#### Description

Pain

#### Timepoint

1,6,12,24 hour After the operation, and also a week after  
the operation

#### Method of measurement

Visual Analogue Scale (VAS)

### 2

#### Description

Consumable Pethidine

#### Timepoint

Up to 24 hours after surgery

#### Method of measurement

Patient document

### 3

#### Description

Consumable Ibuprofen

#### Timepoint

1 to 7 days after surgery

#### Method of measurement

Interview with patient

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Half an hour before the patient leave  
the recovery department, the intervention group will  
receive 500 mg intravenous Methocarbamol (5 cc  
methocarbamol diluted with 5 cc normal saline) and then  
they receive oral Methocarbamol, 1 g, every 8 hrs from 6  
hours until 7 days after the operation.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Half an hour before the patient leave the  
recovery department, the control group will receive 10 cc  
intravenous normal saline. Then they receive oral  
placebo tablets (similar to metocarbamol tablets in  
shape) every 8 hours, from 6 hours until 7 days after the  
operation.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Imam Hossein Educational, Research and Therapeutic Center

**Full name of responsible person**

Mahdi Karimi (Medical intern )

**Street address**

Imam Hossein Hospital, 28 m. End of Ayatollah Towhidi, Imam Street, Shahroud

**City**

Shahroud

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Vice Chancellor for research of Shahroud University of Medical Sciences

**Full name of responsible person**

Mohammad Hasan Emamian

**Street address**

Shahroud University of Medical Sciences, Hafte Tir square, Shahroud

**City**

Shahroud

**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 Shahroud 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**

Shahroud University of Medical Sciences

**Full name of responsible person**

Mahdi Karimi

**Position**

Medical Intern

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

Shahroud University of Medical Sciences, Hafte Tir square, Shahroud

**City**

Shahroud

**Postal code**

۳۶۱۴۷-۷۳۹۴۷

**Phone**

+98 23 3239 5054

**Fax****Email**

info@shmu.ac.ir; mahdi.karimi@shmu.ac.ir

**Web page address**

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Shahroud University of Medical Sciences

**Full name of responsible person**

Naser Mogharabian

**Position**

Renal surgeon and Urogenital tract (urologist)  
Assistant Professor Shahroud University of Medical sc

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

Shahroud University of Medical Sciences, Hafte Tir square, Shahroud

**City**

Shahroud

**Postal code**

۳۶۱۴۷-۷۳۹۴۷

**Phone**

+98 23 3239 5054

**Fax****Email**

info@shmu.ac.ir; dr.mogharabian@yahoo.com;  
mahdi.karimi@shmu.ac.ir

**Web page address**

## Person responsible for updating data

#### Contact

**Name of organization / entity**

Shahroud University of Medical Sciences

**Full name of responsible person**

Mahdi Karimi

**Position**

Medical Intern

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

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**Phone**

+98 23 3239 5054

**Fax**

**Email**

mahdi.karimi@shmu.ac.ir:

martin.khatami@gmail.com

**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*