Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)
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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
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Medical Intern
Other areas of specialty/work
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Person responsible for scientific inquiries

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