

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Effect of preoperative apotel on opioid consumption during and after herniorrhaphy

Protocol summary

Summary

This study will be conducted to evaluate the effect of preoperative apotel on opioid consumption during and after herniorrhaphy. 100 patients with hernia in ASA class 1 and 2 who are candidates for herniorrhaphy, will be included in the study if they have inclusion criteria after obtaining informed consent. Patients will be randomly divided into two groups: case group (50 people) and control (50 people) group. Both groups will receive propofol for induction of anesthesia and intubation for anesthetic maintenance. Patients in the case group will receive 15 mg/kg bodyweight apotel (interavenous acetaminophen) half an hour before the start of surgery. Surgery will be performed as usual for patients in both groups. During the surgery, patients will receive 1 mg/kg bodyweight of opioid based on their symptoms of pain such as tachycardia, sweating, skin reflexes and hypertension. At intervals 1, 2, 4, 8, 12 and 24 hours after surgery, pain intensity in patients of both groups will be measured and recorded on the basis of VAS criteria, by a colleague not informed about the kind of drug. Based on the severity of pain, patients will be administered an analgesic drug (pethidine) and they will not be given another medication as a preanesthetic medication.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201701258375N11**

Registration date: **2017-10-02, 1396/07/10**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-10-02, 1396/07/10

Registrant information

Name

Seyed Amirkazem Vejdan

Name of organization / entity

Birjand University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 56 3222 2300

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vejdan_sa@bums.ac.ir

Recruitment status

Recruitment complete

Funding source

Research approved budget from the deputy of research and technology of Birjand University of Medical Sciences

Expected recruitment start date

2017-05-15, 1396/02/25

Expected recruitment end date

2017-10-17, 1396/07/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of preoperative apotel on opioid consumption during and after herniorrhaphy

Public title

Effect of apotel injection on opioid consumption

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Inguinal hernia; surgical candidate for ASA classes 1 and 2; age 20-50 years Exclusion criteria: drug addiction; history of chronic diseases, diabetes, heart failure, hypertension etc; neuropsychological

diseases
Age
From **20 years** old to **50 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized

Randomization description
Blinding (investigator's opinion)
Double blinded

Blinding description
Placebo

Not used
Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Birjand University of Medical Sciences
Street address
Birjand University of Medical Sciences, Ghaffari street,
Birjand
City
Birjand
Postal code
Approval date
2016-11-15, 1395/08/25
Ethics committee reference number
lr.bums.REC.1395.165

Health conditions studied

1

Description of health condition studied
Post-operative pain control
ICD-10 code
R52.0
ICD-10 code description
Acute pain

Primary outcomes

1

Description

Mean of opioid consumption
Timepoint
1, 2, 4, 8, 12 and 24 hours after surgery
Method of measurement
mg/kg

Secondary outcomes

1

Description
Pain
Timepoint
1, 2, 4, 8, 12 and 24 hours after surgery
Method of measurement
VAS

Intervention groups

1

Description
Patients in the case group will receive 15 mg/kg bodyweight apotel (interavenous acetaminophen) half an hour before the start of surgery. Surgery will be performed as usual and then, based on the pain intensity, an analgesic drug (pethidine) will be given to the patients and they will not receive another medication as preanesthetic medication.

Category
Treatment - Drugs

2

Description
In the patients of control group, surgery is performed as usual, and after then, based on the pain intensity, an analgesic drug (pethidine) will be given to the patients and they will not receive another medication as preanesthetic medication

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Reza Hospital, Birjand
Full name of responsible person
Motahhar Motahhari
Street address
City
Birjand

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research deputy Birjand University of Medical Science

Full name of responsible person

Tuba Kazemi

Street address

Birjand University of Medical Sciences, Ghaffari street, Birjand

City

Birjand

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Research deputy Birjand University of Medical Science

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**

Birjand University of Medical Sciences

Full name of responsible person

Dr Seyed Amirkazem Vejdani

Position

Associate Professor of General Surgery

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Full name of responsible person

Dr Seyed Amirkazem Vejdani

Position

Associate professor

Other areas of specialty/work**Street address****City****Postal code****Phone**

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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