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

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Seyed Amirkazem Vejdan
Name of organization / entity
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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
Ir.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
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Birjand University of Medical Sciences, Ghaffari street, Birjand
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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
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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