Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

A clinical trial comparing the effect of pethidine and ketorolac on the control of acute pain and postoperative complications of hemorrhoidectomy in patients with hemorrhoids

Protocol summary

Study aim

To compare the effect of pethidine and ketorolac on the control of acute pain and postoperative complications of hemorrhoidectomy in patients with hemorrhoids

Design

90 patients undergoing hemorrhoidectomy in the operating ward of Imam Reza Hospital of Birjand will be divided into two equal groups by simple random allocation to receive either pethidine or ketorolac. All the patients will undergo anesthesia in the same way. The group receiving pethidine will have 0.5 mg/kg of pethidine intravenously immediately after the operation, and will then take the drug at a dose of 50 mg 3 times a day for one day. The group receiving ketorolac will take 0.9 mg/kg of ketorolac intravenously immediately after the operation and will then have 30 mg of the drug three times a day for one day.

Settings and conduct

In this study, 90 patients who are eligible for inclusion in the study will be selected via convenience sampling method. They will be randomly assigned into two intervention groups and each participant will be assigned a code.

Participants/Inclusion and exclusion criteria

Main inclusion criterion involves patients with hemorrhoids in ASA class I and class II aged 18 years and older. Major exclusion criteria: regular or substantial use of opiate, sedative, and tranquilizing drugs; history of pulmonary, hepatic, and renal problems; and history of abdominal surgery.

Intervention groups

Intervention Group 1: The group will have 0.5 mg/kg of pethidine intravenously immediately after the operation, and then takes this drug at a dose of 50 mg 3 times a day for one day. Intervention Group 2: The group will take 0.9 mg/kg of ketorolac intravenously immediately after the operation and will then have 30 mg of the drug three times a day for one day.

Main outcome variables

Pain severity; complications including nausea, vomiting, and active post-operative bleeding; and patient satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140519017756N44**
Registration date: **2018-08-21, 1397/05/30**
Registration timing: **registered_while_recruiting**

Last update: **2018-08-21, 1397/05/30**
Update count: **0**

Registration date

2018-08-21, 1397/05/30

Registrant information

Name
Mohammad Bagher Roozgar
Name of organization / entity
Birjand University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 56 3239 5680
Email address
mbroozgar@bums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-29, 1397/03/08

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial comparing the effect of pethidine and ketorolac on the control of acute pain and postoperative complications of hemorrhoidectomy in patients with hemorrhoids

Public title

Impact of ketorolac and peptidine on the control of acute pain and post-operative complications of hemorroidectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with hemorrhoids in ASA class I and class II Age older than 18 years Informed consent for participation

Exclusion criteria:

Regular or substantial use of opiate, sedative, and tranquilizing drugs History of pulmonary, hepatic, renal problemsHistory of abdominal surgery Drug addiction and smoking History of allergy to non-steroidal anti-inflammatory drugs Brucellosis asthma, pregnancy, preeclampsia, and coagulation disorders

Age

From **18 years** old

Gender

Both

Phase

1-2

Groups that have been masked

- Participant

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

After the participants are included in the study, they will be allocated to the study groups randomly via sortification (simple allocation method).

Blinding (investigator's opinion)

Single blinded

Blinding description

Explanations will be provided to the participants concerning the study protocol. However, they will not be aware of the drug they will receive.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Birjand University of Medical Sciences

Street address

Ghaffari St.

City

Birjand

Province

South Khorasan

Postal code

9717853577

Approval date

2018-05-28, 1397/03/07

Ethics committee reference number

IR.BUMS.REC.1397.048

Health conditions studied

1

Description of health condition studied

hemorrhoid

ICD-10 code

K64.9

ICD-10 code description

Unspecified hemorrhoids

Primary outcomes

1

Description

pain severity

Timepoint

0, 6, 12, and 24 hours after operation

Method of measurement

Visual Analogue Scale

2

Description

Nausea

Timepoint

0, 6, 12, and 24 hours after operation

Method of measurement

Inquiry from the patient

3

Description

vomiting

Timepoint

0, 6, 12, and 24 hours after operation

Method of measurement
Inquiry from the patient

4

Description
Active post-operative bleeding
Timepoint
0, 6, 12, and 24 hours after operation
Method of measurement
Inquiry from the patient

5

Description
patient satisfaction
Timepoint
24 hours after operation
Method of measurement
inquiry from the patient

Secondary outcomes

empty

Intervention groups

1

Description
Intervention Group 1 (pethidine): The group will have 0.5 mg / kg of pethidine intravenously immediately after the end of operation, and then takes this drug at a dose of 50 mg 3 times a day for one day.
Category
Treatment - Drugs

2

Description
Intervention Group 2 (ketorolac): The group will take 0.9 mg / kg of ketorolac intravenously immediately after the operation and will then have 30 mg of the drug three times a day for one day.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Operating department of Imam Reza Hospital
Full name of responsible person
Dr Mohammadreza Ghasemianmoghadam
Street address
Taleghani St.
City
Birjand
Province
South Khorasan
Postal code
9717853577
Phone
+98 56 3239 5000
Email
dr.ghasemian54@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
Dr Tooba Kazemi
Street address
Ghaffari Ave.
City
Birjand
Province
South Khorasan
Postal code
9717853577
Phone
+98 56 3238 1200
Email
dr.toobakazemi@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Birjand University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
Davood Asadian Ghahfarokhi
Position
Medical student
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
Street address
Ghaffari St.
City

Birjand
Province
South Khorasan
Postal code
9717853577
Phone
+98 56 3239 5600
Email
asadian.davood@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
Dr Tooba Kazemi
Position
Professor
Latest degree
Specialist
Other areas of specialty/work
Cardiology
Street address
Ghaffari Ave.
City
Birjand
Province
South Khorasan
Postal code
9717853577
Phone
+98 56 3238 1200
Email
drtoobakazemi@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
Mohammad Bagher Roozgar
Position
PhD Candidate in Translation Studies
Latest degree
Master
Other areas of specialty/work
Street address
Ghaffari St.,
City
Birjand,
Province
South Khorasan
Postal code
9717853577
Phone
+98 56 3239 5680
Fax
Email
Roozgar@BUMS.AC.IR
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Not applicable
Title and more details about the data/document
Deidentified Individual Participant Data Set
When the data will become available and for how long
After the paper extracted from the project is published and for 6 months
To whom data/document is available
researchers
Under which criteria data/document could be used
for research purposes
From where data/document is obtainable
personal correspondence with the corresponding author
What processes are involved for a request to access data/document
personal correspondence via email
Comments