

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jul 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 hemorrhoidectomy

**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 problems History 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

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Taleghani St.

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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

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Ghaffari Ave.

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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

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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  
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## 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**  
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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