

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluating The Role of Intravenous Ketorolac in Preventing Post-Operative Pain in Patients Undergoing hemorrhoidectomy: a clinical trial

#### Protocol summary

##### Study aim

Evaluating The Role of Intravenous Ketorolac in Preventing Post-Operative Pain in Patients Undergoing Hemorrhoidectomy in Namazi Hospital, Shiraz, Iran in 1403

##### Design

control group, with parallel groups, double-blind, randomized, phase 2 on 60 patients with randomized block method. After ethical approval and consent, we perform randomization and blinding to reduce bias. Continuously monitor the vital signs and report findings.

##### Settings and conduct

The case group will receive 30 mg ketorolac intravenously just before anesthesia induction and the control group would receive pethidine post-operation, as needed. pain severity assessed in one and four hours after operation in both case and control groups by give a score to their pain from 0 (no pain) to 10 (severe pain). Pain severity and duration, type and dose of post-op analgesic use, type and dose of sedative drug, blood pressure, heart rate, patients' demographic data will be recorded. patients and physician assessing them post-op are unaware whether the patient is in the control or case group

##### Participants/Inclusion and exclusion criteria

patients with planned hemorrhoidectomy in Namazi hospital, Shiraz, Iran. Patients with drug addiction, positive history of anxiety disorder, mental problems, sensory problems, thrombotic hemorrhoids, or who underwent local or spinal anesthesia will be excluded from the study.

##### Intervention groups

The control group will undergo routine care for post-hemorrhoidectomy operations, but the case group will receive 30 mg of Ketorolac intravenously before the operation.

##### Main outcome variables

pain degrees evaluated by asking patients to give a score from 0 (no pain) to 10 (severe pain). duration of

pain assessed in both groups. Pain severity and duration, type and dosage of post-op analgesic use, type and dose of sedative drug, blood pressure, heart rate, along with patients' demographic data will be recorded.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20240808062692N1**

Registration date: **2025-01-02, 1403/10/13**

Registration timing: **registered\_while\_recruiting**

Last update: **2025-01-02, 1403/10/13**

Update count: **0**

##### Registration date

2025-01-02, 1403/10/13

##### Registrant information

##### Name

Hooman Rezaei

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

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##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-09-22, 1403/07/01

##### Expected recruitment end date

2025-03-19, 1403/12/29

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Evaluating The Role of Intravenous Ketorolac in Preventing Post-Operative Pain in Patients Undergoing hemorrhoidectomy: a clinical trial

**Public title**

Evaluating The Role of Intravenous Ketorolac in Preventing Post-Operative Pain in Patients Undergoing hemorrhoidectomy

**Purpose**

Prevention

**Inclusion/Exclusion criteria****Inclusion criteria:**

patients with planned hemorrhoidectomy who are referred to Namazi hospital, Shiraz, Iran

**Exclusion criteria:**

drug addiction positive history of anxiety disorder or mental problems or sensory problems thrombotic hemorrhoids whom underwent local or spinal anesthesia

**Age**From **18 years** old**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**Target sample size: **60****Randomization (investigator's opinion)**

Randomized

**Randomization description**

block randomization method randomizing participants within blocks such that an equal number are assigned to each treatment we have 30 cases (patients receiving ketorolac) and 30 controls (patients not receiving ketorolac). We'll use block randomization to ensure balanced groups. Here's how you can do it: Determine Block Size: Let's choose a block size of 6 (you can adjust based on preference). This will mean each block contains an equal number of cases and controls. Create Block Sequences: For a block size of 6, you have these possible sequences: KKKCCC KKCKCC KKCCCK KCCKKC CCKKKC CCKCKK CCKCKK CCCKKK and so on... Randomize Block Selection: Randomly select one of these sequences for each block of 6 participants. Assign Participants: As participants are enrolled, assign them to treatment groups according to the selected block sequence. Repeat this process for each new block until all participants are assigned. Here's a simplified example of how it might look for the first few blocks: Block Number Block Sequence Participant Assignments Block 1 KKKCCC 1-K,

2-K, 3-K, 4-C, 5-C, 6-C Block 2 KKCCCK 7-K, 8-K, 9-C, 10-C, 11-K, 12-C Block 3 CKCKKC 13-C, 14-K, 15-C, 16-K, 17-K, 18-C ... .. Repeat this until all 60 participants are assigned. This method ensures each group has a balanced number of participants, reducing bias and improving the reliability of your results.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

the patients would not know which group they are and the physician assessing them post-operation also is unaware whether the patient is in the control or case group A clinical trial design in which neither the participants nor investigators know which participants are receiving the experimental medicine and which are receiving a placebo (or comparator therapy). Double-blind trials are thought to produce objective results, since the expectations of the investigator and the participant do not affect the outcome. Also called double-masked trial. Considered best-controlled trial design. Decreased chance of preconceived notions or physical cues (e.g. the placebo effect, observer bias, experimenter's bias) to distort the results. The key that identifies the participants and which group they belonged to is kept by a third party, and is not revealed to the researchers until the study is over. Should be used whenever possible. In trials in studies comparing two active compounds (test medicine and comparator) and when the two treatments cannot be made identical, double dummy is a technique for retaining the blind. Supplies are prepared for Treatment A (active and indistinguishable placebo) and for Treatment B (active and indistinguishable placebo). Participants then take two sets of treatment; either A (active) and B (placebo), or A (placebo) and B (active). For example, if we want to compare two medicines, one presented as green tablets and one as pink capsules, we could also supply green placebo tablets and pink placebo capsules so that both groups of patients would take one green tablet and one pink capsule.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Shiraz University of Medical Sciences

**Street address**

Zand Street, Shiraz University of Medical Sciences

**City**

Shiraz

**Province**

Fars

**Postal code**

8447171946

**Approval date**

2024-07-07, 1403/04/17

**Ethics committee reference number**

IR.SUMS.MED.REC.1403.268

**Health conditions studied****1****Description of health condition studied**

hemorrhoid

**ICD-10 code**

K64.2

**ICD-10 code description**

Third degree hemorrhoids

**Primary outcomes****1****Description**

pain degree

**Timepoint**

one and four and 24 hours after operation

**Method of measurement**

Subjective score of pain from 0 (no pain) to 10 (severe pain)

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: The case group received 30 mg ketorolac intravenously immediately before induction of anesthesia and received pethidine after the operation if needed. The intensity of pain one and four hours after the operation in case group is evaluated by asking the patients to give a pain score from 0 (no pain) to 10 (severe pain). The intensity and duration of pain, the type and dosage of postoperative painkillers, the type and dosage of sedatives, blood pressure, heart rate, and the demographic information of the patients are recorded. The patients do not know which group they belong to, and the doctor evaluates them after the operation. He also does not know whether the patient is in the control or case group.

**Category**

Prevention

**2****Description**

Control group: The control group did not receive any

medication before the induction of anesthesia and received pethidine after the operation if needed. The intensity of pain one and four hours after the operation in the control group is evaluated by asking the patients to give a pain score from 0 (no pain) to 10 (severe pain). The intensity and duration of pain, the type and dosage of postoperative painkillers, the type and dosage of sedatives, blood pressure, heart rate, and the demographic information of the patients are recorded. The patients do not know their group, and the doctor evaluates them after the operation. He also does not know whether the patient is in the control or case group.

**Category**

Prevention

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Namazi hospital

**Full name of responsible person**

Ahmad Hoseinzade

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

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**Full name of responsible person**

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

Yes

**Title of funding source**

Shiraz 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**

Shiraz University of Medical Sciences

**Full name of responsible person**

Hooman Rezaei

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

General Surgery

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**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**

Yes - There is a plan to make this available

**Title and more details about the data/document**

Whole data

**When the data will become available and for how long**

6 months after publication

**To whom data/document is available**

Everyone

**Under which criteria data/document could be used**

No conditions are required

**From where data/document is obtainable**

Hooman Rezaei Email : hoomanr2000@gmail.com

**What processes are involved for a request to access data/document**

email the publisher and you can have the data as soon

as possible

**Comments**