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 ۳۰ 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 ۰ (no pain) to ۱۰ (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 ۳۰ mg of Ketorolac intravenously before the operation.

Main outcome variables

pain degrees evaluated by asking patients to give a score from ۰ (no pain) to ۱۰ (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
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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 KKCCKC 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 KKCCKC 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 ۰ (no pain) to ۱۰ (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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Namazi square
City
Shiraz
Province
Fars
Postal code
۱۳۳۱۱۷۱۹۳۶
Phone
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Email
nemazee_inf@sums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Seyed Vahid hoseini
Street address
Zand street
City
Shiraz
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Fars
Postal code
7134814336
Phone
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Email
info@sums.ac.ir
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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Assistant professor

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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