

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

A Study of The effect of infiltrative ketorolac on pain relief after hemorrhoidectomy

Protocol summary

Registration timing: **registered_while_recruiting**

Study aim

Determining the effect of topical ketorolac on pain control after hemorrhoidectomy

Last update: **2021-09-30, 1400/07/08**

Update count: **0**

Design

Two-way blind randomized clinical trial with parallel groups of two to three phases on 84 patients using numerical rating scale (N R S)Enters SPSS software version 21.

Registration date

2021-09-30, 1400/07/08

Settings and conduct

In this double-blind study, 84 patients with hemorrhoidectomy will attend Ali Ibn Abitaleb Hospital in Rafsanjan.

Registrant information

Name

Negin Shahrokhzadeh kermani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3429 8129

Email address

neginshahrokhzadeh@yahoo.com

Participants/Inclusion and exclusion criteria

Entry requirements for ages 15 to 55, ASA I-II Absence: Patients with Coagulation diseases and patients with a history of gastrointestinal bleeding or peptic ulcer and drug-related patients with a history of uncontrolled diabetes and hypertension and patients who have not received the drug in the 8 hours before surgery.

Recruitment status

Recruitment complete

Funding source

Intervention groups

Intervention group 1: At the end of the surgery, 4 cc of half a percent marcaine and 1 cc of ketorolac are infiltrated at the surgery site. Intervention group 2: At the end of the surgery, 4 cc of half a percent marcain is injected at the surgical site and 1 cc of ketorolac is injected at the same time. Intervention group 3: At the end of the surgery, 4% of the markain is infiltrated by half a percent at the surgical site.

Expected recruitment start date

2021-05-01, 1400/02/11

Expected recruitment end date

2021-11-02, 1400/08/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Main outcome variables

Pain score, pain measurement time, received medication, age, sex

Scientific title

A Study of The effect of infiltrative ketorolac on pain relief after hemorrhoidectomy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210922052556N1**

Registration date: **2021-09-30, 1400/07/08**

Public title

The effect of infiltrative ketorolac on pain relief after hemorrhoidectomy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
ASA I - II patients 15 to 55 years of age

Exclusion criteria:
Patients with coagulation diseases Patients with a history of gastrointestinal bleeding or a history of gastrointestinal ulcers Drug-dependent patients Patients with a history of diabetes and uncontrolled hypertension Patients who received opioid for pain control 8 hours before surgery.

Age
From **15 years** old to **55 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **84**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, each participant is given a unique code that analyzes the data and participants are unaware of which group the assigned code belongs to.

Placebo
Not used

Assignment
Parallel

Other design features
Participants in this study are divided into three intervention (case) groups.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

کمیته اخلاق دانشکده علوم پزشکی رفسنجان

Street address

Imam Ali St. Ali Ibn Abitaleb Hospital

City

Rafsanjan

Province

Kerman

Postal code

7717933777

Approval date

2021-01-29, 1399/11/10

Ethics committee reference number

IR.RUMS.REC.1399.242

Health conditions studied

1

Description of health condition studied

Hemorrhoids

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Intensity of pain

Timepoint

Immediately after hemorrhoidectomy and 6 hours after hemorrhoidectomy and 12 hours after hemorrhoidectomy and 24 hours after hemorrhoidectomy

Method of measurement

Using NRS (pain rating system from 0 to 10)

Secondary outcomes

1

Description

Medication received

Timepoint

Immediately after hemorrhoidectomy and 6 hours after hemorrhoidectomy and 12 hours after hemorrhoidectomy and 24 hours after hemorrhoidectomy

Method of measurement

View

Intervention groups

1

Description

Intervention group 1: At the end of the surgery, 4 cc of half a percent marcaine and 1 cc of ketorolac are infiltrated at the surgery site.

Category

N/A

2

Description

Intervention group 2: At the end of the surgery, 4 cc of half a percent marcain is injected at the surgical site and 1 cc of ketorolac injected at the same time.

Category

N/A

3

Description

Intervention group 3: At the end of the surgery, 4% of the markain is infiltrated by half a percent at the surgical site.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali Ibn Abitaleb Hospital in Rafsanjan

Full name of responsible person

Negin Shahrokhzadeh Kermani

Street address

Ali Ibn Abitaleb Hospital ,Imam Ali Blvdlvd.

City

Rafsanjan

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Postal code

7717966996

Phone

+98 34 3429 8129

Email

neginshahrokhzadeh@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Ali Shamsizadeh

Street address

Imam Ali Boulevard, Rafsanjan University of Medical Sciences

City

Rafsanjan

Province

Kerman

Postal code

7717966996

Phone

+98 34 3429 8129

Email

AliShamsy@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Rafsanjan 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

Rafsanjan University of Medical Sciences

Full name of responsible person

Negin Shahrokhzadeh Kermani

Position

Resident anesthesia

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

Street address

No. 16 Laleh Ave.

City

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Province

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Postal code

7717966996

Phone

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Email

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available