

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Comparing the effect of diclofenac and acetaminophen suppositories in decrease pain following hemorrhoidectomy

Protocol summary

Study aim

Determination of Effect of Diclofenac Suppository with Acetaminophen Suppository on Reducing Pain following Hemorrhoidectomy

Design

Clinical trials have two groups, parallel groups, patients who are candidates for hemorrhoidectomy, randomized Double blinded

Settings and conduct

The study would be held in Imam Ali hospital, Zahedan for patients who are candidates for hemorrhoidectomy. The study is double blind as the investigator and the patients will not be aware of the suppository types.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients undergoing hemorrhoidectomy in Imam Ali Hospital, Zahedan/
Exclusion criteria: History of coagulation disorder, Daily oral intake of NSAID, Alcohol or drug abuse, obvious liver or alcoholic diseases, Asthma, Chronic obstructive pulmonary disease, History of peptic ulcer

Intervention groups

The groups are divided into two groups: the first group takes 2 doses of 325 mg of acetaminophen suppositories which is 650 mg and the second group of diclofenac suppositories is 100 mg.

Main outcome variables

Amount of pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190128042525N2**

Registration date: **2019-04-27, 1398/02/07**

Registration timing: **retrospective**

Last update: **2019-04-27, 1398/02/07**

Update count: **0**

Registration date

2019-04-27, 1398/02/07

Registrant information

Name

Gholamreza Bazmandegan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3428 0185

Email address

clinical.research@rums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2014-06-02, 1393/03/12

Expected recruitment end date

2016-12-02, 1395/09/12

Actual recruitment start date

2014-11-07, 1393/08/16

Actual recruitment end date

2017-01-14, 1395/10/25

Trial completion date

2017-03-06, 1395/12/16

Scientific title

Comparing the effect of diclofenac and acetaminophen suppositories in decrease pain following hemorrhoidectomy

Public title

Diclofenac and acetaminophen in hemorrhoidectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All patients undergoing hemorrhoidectomy in Imam Ali

Hospital

Exclusion criteria:

History of coagulation disorder
Daily oral intake of NSAID
Alcohol or drug abuse liver or alcoholic disease
Asthma
Chronic obstructive pulmonary disease
History of peptic ulcer

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **70**

Actual sample size reached: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Selection and assignment of samples to each treatment group will be done by random blocking method. Therefore, according to the sample size of 70 cases, 9 blocks were defined with 8 patients per block which are equally placed in each block of the groups. Then the tabs are arranged for each of the groups according to the random distribution in each block. So, upon completion of each block, 8 patients will be enrolled in the study, which will be equal to 4 patients from each group.

Blinding (investigator's opinion)

Double blinded

Blinding description

The investigator and Data analyzer will not be informed of the type of study group (type of suppository that will be consumed in each group). At the beginning of the study, all participants will be given study conditions and the two types of drugs which will be used, but none of them will be aware in which group they will be assigned.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Zahedan University of Medical Sciences

Street address

ZAUMS Main campus, Zahedan, Sistan and

Baluchestan, Iran

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Approval date

2013-12-31, 1392/10/10

Ethics committee reference number

IR.Zaums.REC.1392.967

Health conditions studied

1

Description of health condition studied

hemorrhoidectomy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Amount of pain

Timepoint

Zero times (recovery) 2.4, 12 24 hours after the patient's operation

Method of measurement

Visual analogue score

Secondary outcomes

empty

Intervention groups

1

Description

Intervention Group 1: two suppositories of acetaminophen 325 mg equal to 650 mg.

Category

Treatment - Drugs

2

Description

Intervention Group 2: Diclofenac suppository 100 mg

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali_Ibne_Abitaleb Hospital

Full name of responsible person

Ismail Elahabadi
Street address
Salamat Blvd., Khalij-e-Fars Highway, Iran
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
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Web page address
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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

Zahedan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Private

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
Ismail Elahabadi
Position
General Surgeon, Assistant professor
Latest degree
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Other areas of specialty/work
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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

"There is no further information"

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available