

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

A clinical trial comparing topical Metronidazole gel and conventional dressing on wound healing after hemorrhoidectomy

Protocol summary

Study aim

To compare the conventional dressing and topical metronidazole gel in wound healing of operated hemorrhoids

Design

The sample size is 112 patients who will be allocated into case and control groups via randomized allocation method (n=56 per group).

Settings and conduct

This study will be performed on patients referred to the Birjand-based Imam Reza Hospital with internal hemorrhoid without complications. Neither the patient nor the nurse collecting the data will be informed of the dressing type applied.

Participants/Inclusion and exclusion criteria

This study will be performed on patients referred to the Birjand-based Imam Reza Hospital with internal hemorrhoid without complications. The main inclusion criteria consist of informed consent; patients with internal hemorrhoids without complication; and age between 20 and 60 years. Major exclusion criteria involve unwillingness to continue participation; presence of background diseases (such as hypertension, cardiovascular diseases, pulmonary diseases, diabetes mellitus); anal fissure; and addiction to drugs.

Intervention groups

In the control group, we will use conventional dressing and in the case group, we will use topical metronidazole gel.

Main outcome variables

Post-operative pain and the degree of epithelization will be assessed.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT201604108375N9**

Registration date: **2017-08-06, 1396/05/15**

Registration timing: **registered_while_recruiting**

Last update: **2018-01-22, 1396/11/02**

Update count: **1**

Registration date

2017-08-06, 1396/05/15

Registrant information

Name

Seyed Amirkazem Vejdani

Name of organization / entity

Birjand University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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vejdani_sa@bums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice-chancellery for Research of Birjand University of Medical Sciences

Expected recruitment start date

2017-07-23, 1396/05/01

Expected recruitment end date

2018-03-21, 1397/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial comparing topical Metronidazole gel and conventional dressing on wound healing after hemorrhoidectomy

Public title

Effects of topical Metronidazole gel and conventional dressing on wound healing

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Informed consent patients with internal hemorrhoids without complication age between 20 and 60 years

Exclusion criteria:

Unwillingness to continue participation presence of background diseases (such as hypertension, cardiovascular diseases, pulmonary diseases, diabetes mellitus) anal fissure addiction to drugs fistula abscesses

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

1-2

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **112**

Randomization (investigator's opinion)

Randomized

Randomization description

The participants were allocated into study groups using table of random numbers.

Blinding (investigator's opinion)

Double blinded

Blinding description

Neither the patient nor the nurse collecting the data will be informed of the dressing type applied.

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

Vice-chancellery of Research and Technology, Birjand University of Medical Sciences, Ghaffari St.,

City

Birjand

Province

South Khorasan

Postal code

9717853577

Approval date

2017-07-22, 1396/04/31

Ethics committee reference number

IR.BUMS.REC.1396.118

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

Internal haemorrhoids without complication

ICD-10 code

I84.2

ICD-10 code description

Internal haemorrhoids NOS

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

Wound healing

Timepoint

Days 3, 7, 14 and 21 after the intervention

Method of measurement

Physical examination for epithelization

Secondary outcomes**1****Description**

Pain severity

Timepoint

6, 12, 24, and 48 hours and days 7 and 14 after the intervention

Method of measurement

Visual Analogue Scale

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

Intervention group (Topical Metronidazole gel dressing): In the case group, topical metronidazole gel will be applied in wound healing of operated hemorrhoids. Visual Analogue Scale will be employed to measure pain and an expert surgeon will visit the patient to evaluate the degree of epithelization.

Category

Treatment - Other

2**Description**

Control Group (Traditional wound dressing): In the control group, we will use conventional dressing. Visual Analogue Scale will be employed to measure pain and an

expert surgeon will visit the patient to evaluate the degree of epithelization.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Educational Hospital

Full name of responsible person

Dr. Seyed Amirkazem Vejdani

Street address

Surgery Ward, Imam Reza Educational Hospital,
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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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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

Fahime Shirdel

Position

Medical Student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Dr Seyed Amirkazem Vejdani

Position

General Surgeon

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Specialist

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General Surgery

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

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Web page address**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

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Deidentified IPD: If there is a request, we will consider it.

When the data will become available and for how long

Since the time the extracted paper is published for 6 months

To whom data/document is available

Researchers who are interested in this subject matter

Under which criteria data/document could be used

Applicants can present their requests via email of researchers as posited in the extracted paper.

From where data/document is obtainable

Via personal correspondence

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

An applicant should provide details of the research project undertaken by him/her via email to us. Within a week, the data may be provided.

Comments