

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 2026

### Evaluation of the efficacy of topical sucralfate on hemorrhoidectomy wound healing process and pain severity

#### Protocol summary

##### Study aim

Determination of a functional method for decreasing the pain after hemorrhoidectomy.

##### Design

40 patients undergoing open hemorrhoidectomy in the city of Birjand who referred to Imam Reza hospital were picked for this study and were divided into two groups using accidental randomization. This is a single blinded clinical trial.

##### Settings and conduct

This is a single blinded study and is performed in the surgery ward of Imam Reza hospital in Birjand university of medical sciences.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients who underwent hemorrhoidectomy. Exclusion criteria: Diabetes, drug abuse, other specific diseases

##### Intervention groups

Investigation group: In the investigation group, after open hemorrhoidectomy and complete homeostasis a gauze with 10% sucralfate ointment will be applied on the operation site and the patient will be transferred to recovery. The gauze will be placed inside the anal canal for 24 hours. After that the sucralfate ointment will be applied by the patient after each defecation and then the two variables will be measured. (1) The pain level will be measured by the VAS score 24 hours after the operation, and after that in 4-day periods until the end of epithelialization; (2) Epithelialization will be examined in 3-day periods by surgeon. Control group: In the control group, after open hemorrhoidectomy and complete homeostasis a gauze with placebo (vaseline) will be applied on the operation site and patient will be transferred to recovery. The gauze will be placed inside the canal for 24 hours. After that the placebo (vaseline) will be applied by the patient after each defecation and then the two variables will be measured as in the investigation group.

##### Main outcome variables

Pain and the amount of epithelialization

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20111211008375N17**

Registration date: **2018-09-23, 1397/07/01**

Registration timing: **retrospective**

Last update: **2018-09-23, 1397/07/01**

Update count: **0**

##### Registration date

2018-09-23, 1397/07/01

##### Registrant information

##### Name

Seyed Amirkazem Vejdan

##### Name of organization / entity

Birjand University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 56 3222 2300

##### Email address

vejdan\_sa@bums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-05-10, 1396/02/20

##### Expected recruitment end date

2017-09-21, 1396/06/30

##### Actual recruitment start date

2017-05-10, 1396/02/20

##### Actual recruitment end date

2017-09-21, 1396/06/30

## Trial completion date

empty

## Scientific title

Evaluation of the efficacy of topical sucralfate on hemorrhoidectomy wound healing process and pain severity

## Public title

Evaluation of the efficacy of topical sucralfate on hemorrhoidectomy wound healing process and pain severity

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Patients who had hemorrhoidectomy surgery.

### Exclusion criteria:

Diabetes Drug abuse Other specific diseases

## Age

No age limit

## Gender

Both

## Phase

2-3

## Groups that have been masked

- Participant

## Sample size

Target sample size: **40**

Actual sample size reached: **40**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Balanced block randomization

## Blinding (investigator's opinion)

Single blinded

## Blinding description

This study is conducted as a single blinded investigation for participants. The main reason for single blinding is the absence of another surgeon for the study.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethical committee of Birjand University of Medical Sciences

##### Street address

Ghaffari St

##### City

Birjand

##### Province

South Khorasan

##### Postal code

9717853577

##### Approval date

2017-03-05, 1395/12/15

##### Ethics committee reference number

lr.bums.REC.1395.264

## Health conditions studied

### 1

#### Description of health condition studied

The effect of topical sucralfate on hemorrhoidectomy wound healing process .

#### ICD-10 code

K64.1

#### ICD-10 code description

Second degree hemorrhoids

## Primary outcomes

### 1

#### Description

Pain

#### Timepoint

The first 24 hours after operation and after that in 4-day periods until the end of epithelialization

#### Method of measurement

VAS

### 2

#### Description

Epithelialization

#### Timepoint

Every 3 days until complete epithelialization

#### Method of measurement

Rectal examination by surgeon

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Investigation group: In the investigation group, after open hemorrhoidectomy (by Milligan-Morgan method) and complete homeostasis and ensuring of the absence of bleeding, a gauze with 10% sucralfate ointment will be applied on the operation site and the patient will be transferred to recovery. The gauze will be placed inside the anal canal for 24 hours. After that the sucralfate ointment will be applied by the patient after each defecation.

#### Category

Treatment - Drugs

**2**

### Description

Control group: In this group, after open hemorrhoidectomy (by Milligan-Morgan method) and complete homeostasis and ensuring of the absence of bleeding, a gauze with placebo(vaseline) will be applied on the operation site and patient will be transferred to recovery.The gauze will be placed inside the canal for 24 hours. After that the placebo (vaseline) will be applied by the patient after each defecation.

### Category

Placebo

## Recruitment centers

**1**

### Recruitment center

#### Name of recruitment center

Emam Reza Hospital

#### Full name of responsible person

Seyyed AmirKazem Vejdani

#### Street address

Taleghani street

#### City

birjand

#### Province

South Khorasan

#### Postal code

9714811151

#### Phone

+98 56 3222 2300

#### Email

vejdani\_sa@bums.ac.ir

## Sponsors / Funding sources

**1**

### Sponsor

#### Name of organization / entity

Birjand University of Medical Sciences

#### Full name of responsible person

Dr Tuba Kazemi

#### Street address

Ghaffari Street , Birjand University of Medical Sciences

#### City

Birjand

#### Province

South Khorasan

#### Postal code

9714811151

#### Phone

+98 56 3244 0388

#### Email

drtooba.kazemi@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

Dr Amir kazem vejdani

#### Position

Specialist in general surgery, Associate professor

#### Latest degree

Specialist

#### Other areas of specialty/work

General Surgery

#### Street address

Imam Reza hospital

#### City

Birjand

#### Province

South Khorasan

#### Postal code

9714811151

#### Phone

+98 56 3222 2300

#### Email

vejdani\_sa@bums.ac.ir

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Birjand University of Medical Sciences

#### Full name of responsible person

Dr Amir Kazem Vejdani

#### Position

Specialist in general surgery, Associate professor

#### Latest degree

Specialist

#### Other areas of specialty/work

General Surgery

#### Street address

Taleghani St

#### City

Birjand

#### Province

South Khorasan  
**Postal code**  
9714811151  
**Phone**  
+98 56 3222 2300  
**Email**  
vejdan\_sa@bums.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Birjand University of Medical Sciences  
**Full name of responsible person**  
maryam daneshmand  
**Position**  
Medical student  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
General Surgery  
**Street address**  
No.31, saa'di 3 St, Moallem Blvd  
**City**  
Birjand  
**Province**  
South Khorasan  
**Postal code**  
9714811151  
**Phone**  
+98 56 3243 3872  
**Email**  
maryamd669@gmail.com

## 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

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

Yes - There is a plan to make this available

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

The shared data will include a patient-specific file for both control and intervention groups, including age and gender, and the patients responses in each step of the study to any intervention. This includes only parts of the entire data.

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

Data access starts in 1398 (2020) and ends in 1400 (2022).

### To whom data/document is available

The data can be sent to all students and researchers affiliated to medical universities of Iran.

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

The applicants must provide the general information about their place of employment or university, the student number and the reason for requesting this information in their request e-mail. Obviously, if they have the data, they can perform tests in order to verify the accuracy of the statistical analysis. but any other use Without the permission of the researcher of this study is not allowed.

### From where data/document is obtainable

Applicants can send their requests to Doctor Vejdan by this e-mail address : vejdan\_sa@bums.ac.ir

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

Any eligible applicant must send an e-mail to: vejdan\_sa@bums.ac.ir including a notice containing their academic and university information and the purpose of the data request, and then after a maximum of 4 weeks, the data file will be received from the above e-mail address.

### Comments