Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 pateints undergoing open hemorrhoidectomy in the city of Birjand who reffered to Emam reza hospital were picked for this study and were divided into two group 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
Ir.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 Vejdan

Street address
Taleghani street

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birjand

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9714811151

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Birjand University of Medical Sciences

Full name of responsible person
Dr Tuba Kazemy

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Ghaffari Street , Birjand University of Medical Sciences

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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 vejdan

Position
Specialist in general surgery, Associate professor

Latest degree
Specialist

Other areas of specialty/work
General Surgery

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Imam Reza hospital

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Birjand University of Medical Sciences

Full name of responsible person
Dr Amir Kazem Vejdan

Position
Specialist in general surgery, Associate professor

Latest degree
Specialist

Other areas of specialty/work
General Surgery

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Person responsible for updating data

Contact

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Full name of responsible person
maryam daneshmand

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Medical student

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General Surgery

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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
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 the from the above e-mail address.

Comments