

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

The comparison of saline enema and bisacodyle in rectal preparation before anorectal surgery

Protocol summary

Summary

This is a randomized clinical trial study. Sixty hospitalized patients for Anorectal surgery (Hemorrhoid, Fisher and Fistula) will be recruited by convenient sampling and then randomly allocated receive 500cc Saline or 6 Bizacodil tablets (from Sobhan company) beginning from a day before operation in order to bowel preparation. Then, participants will be operated with similar anesthesia method. Surgeon's and patient's satisfaction and complications of surgery will be evaluated and compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138905094477N1**
Registration date: **2010-09-16, 1389/06/25**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2010-09-16, 1389/06/25

Registrant information

Name

Ahmad Amouzeshi

Name of organization / entity

Birjand University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 56 1443 0142

Email address

amouzeshiahmad@bums.ac.ir

Recruitment status

Recruitment complete

Funding source

Birjand University of Medical Sciences

Expected recruitment start date

2010-05-25, 1389/03/04

Expected recruitment end date

2011-11-25, 1390/09/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of saline enema and bisacodyle in rectal preparation before anorectal surgery

Public title

The comparison of two different methods in rectal preparation before anorectal surgery

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: age 20-60, hospitalized patients for Anorectal surgery, willingness to participate Exclusion criteria: pregnancy, breast feeding, presence of severe cardiac or renal diseases

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Birjand University of Medical Sciences

Street address

Birjand University of Medical Sciences, Ghafari street

City

Birjand

Postal code

Approval date

2010-06-01, 1389/03/11

Ethics committee reference number

23904

Health conditions studied

1

Description of health condition studied

Chronic anal fissure

ICD-10 code

K60.1

ICD-10 code description

Chronic anal fissure

2

Description of health condition studied

Anal fistula

ICD-10 code

K60.3

ICD-10 code description

Anal fistula

3

Description of health condition studied

Hemorrhoid

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Surgeon's satisfaction

Timepoint

After surgery

Method of measurement

Form that provided by researcher

2

Description

Patient's satisfaction

Timepoint

After surgery

Method of measurement

Form that provided by researcher

Secondary outcomes

1

Description

Operation complications

Timepoint

10 days after surgery

Method of measurement

Check list

Intervention groups

1

Description

500cc Salin the night before surgery

Category

Other

2

Description

6 Bizacodil tablets, every 4 hours, since the noon before surgery

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Hospital

Full name of responsible person

Street address

City

Birjand

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Dr Mohammad Dehghani Firoozabadi

Street address

Birjand University of Medical Sciences, Ghafari street

City

Birjand

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

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Dr Ahmad Amouzeschi

Position

Public surgery/Chancellor for Students Affairs and Culture

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty