

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

The evaluation of Colofac efficacy in treatment of acute anal fissure

Protocol summary

Summary

During this project the patients who come to Bushehr Abolfazl clinic with acute anal fissure symptoms are examined by a general surgeon and they will randomly be divided to two groups if the diagnosis is definitely acute anal fissure. One group (20 cases) will take Colofac and the other group (20 cases) will take routine medicines. Then the patients will be followed up in order to evaluate the effect of the medicine.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201009294840N1**

Registration date: **2011-02-01, 1389/11/12**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-02-01, 1389/11/12

Registrant information

Name

Hamid Reza Alizadeh

Name of organization / entity

Bushehr University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 77 1252 4044

Email address

hr.alizadeh@bpums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Bushehr University Of Medical Sciences

Expected recruitment start date

2009-12-22, 1388/10/01

Expected recruitment end date

2010-12-22, 1389/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The evaluation of Colofac efficacy in treatment of acute anal fissure

Public title

The evaluation of Colofac efficacy in treatment of anal fissure

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: diagnosis is definitely acute anal fissure, age between 15-65 yr. Exclusion criteria: existence of underlying diseases such as cancer (carcinoma, leukemia), IBD, TB, AIDS, STD and syphilis.

Age

From **15 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Bushehr University Of Medical Sciences
Street address
Moallem street
City
Bushehr
Postal code
Approval date
1990-01-01, 1368/10/11
Ethics committee reference number
2320

Health conditions studied

1

Description of health condition studied
Acute Anal Fissure
ICD-10 code
K60.0
ICD-10 code description
Acute anal fissure

Primary outcomes

1

Description
Improvement of ulcer
Timepoint
2 weeks
Method of measurement
Physical Exam

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 135 mg of Colofac every night till treatment of ulcer
Category
Treatment - Drugs

2

Description
Control group: routine methods of anal fissure treatment
Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Abolfazl Clinic
Full name of responsible person
Street address
City
Bushehr

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for Research, Bushehr University Of Medical Sciences
Full name of responsible person
Dr Abdollatif Amini
Street address
Bushehr University Of Medical Sciences
City
Bushehr
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for Research, Bushehr 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
Bushehr University Of Medical Sciences
Full name of responsible person
Raheleh Abolfathi Momtaz
Position
Student Of Medicine

Other areas of specialty/work**Street address**

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City

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Bushehr University Of Medical Sciences

Full name of responsible person

Dr Hamidreza Alizadeh

Position

Surgery Specialist

Other areas of specialty/work**Street address**

Fatemeh Zahra Hospital

City

Bushehr

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Bushehr University Of Medical Sciences

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Raheleh Abolfathi Momtaz

Position

Student Of Medicine

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Web page address**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