

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Comparison of the TPM therapeutic protocol efficacy in chronic anal fissure with classic treatment

Protocol summary

Summary

Objective: comparison of the effect of the treatment protocol based on traditional medicine on chronic anal fissure with classic treatment. The study is a double blind clinical trial in females between 20 and 60 years old with chronic anal fissure diagnosed by a gastroenterologist as a chronic fissure without any underlying diseases (IBD, cancer, abscess and fistula) who passed the eligible criteria are randomly divide into 2 groups. sample size :60 for the first group Diltigel and high fiber diet and for second group herbal gel and avoid from harmful foods for fissure are administer. Intervention time: at least 4 weeks. Primary outcome : a reduction or improvement in the symptoms of patients on the standard scale evaluation (VAS and SF-36) in the start of intervention, 1, 2, 4 weeks after intervention and 4 weeks after the end of intervention .after the relief of symptoms for definitive diagnosis colonoscopy will be done.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017010731808N1**
Registration date: **2017-03-05, 1395/12/15**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-03-05, 1395/12/15

Registrant information

Name

Sedigheh Tavakoli Dastjerdi

Name of organization / entity

Medical university of Mashhad

Country

Iran (Islamic Republic of)

Phone

+98 51 3855 2188

Email address

tavakkolis901@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2017-03-05, 1395/12/15

Expected recruitment end date

2017-10-23, 1396/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the TPM therapeutic protocol efficacy in chronic anal fissure with classic treatment

Public title

The efficacy of herbal ointment in treatment of Anal fissure

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: female with chronic anal fissure between 20 and 60 years old with pain and irritation; no fistula or abscess in the anal area; no history of anal cancer. Exclusion criterion: patients with underlying diseases (crohn disease, ulcerative colitis); sensitivity to drug ingredients; pregnancy or lactation.

Age

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

Gender

Female

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

Vice chancellor for research, Mashad University of Medical Sciences

Street address

Mashad University of Medical Sciences, Ghoreishi Building

City

Mashhad

Postal code

13944-91388

Approval date

2017-01-07, 1395/10/18

Ethics committee reference number

IR.MUMS.REC.1395.483

Health conditions studied

1

Description of health condition studied

Anal fissure

ICD-10 code

K60.1

ICD-10 code description

Chronic anal fissure

Primary outcomes

1

Description

Pain

Timepoint

Before the start of intervention, 1, 2, 4 weeks after intervention and 4 weeks after the end of intervention

Method of measurement

VAS

Secondary outcomes

1

Description

Irritation

Timepoint

Before the start of intervention, 1, 2, 4 weeks after intervention and 4 weeks after the end of intervention

Method of measurement

VAS

2

Description

Bleeding

Timepoint

Before the start of intervention, 1, 2, 4 weeks after intervention and 4 weeks after the end of intervention

Method of measurement

VAS

Intervention groups

1

Description

Intervention group: ITM based protocol local herbal gel from extract of Astragalus fasciculifolius, Comiphora mukul, Syzygium aromaticum: clove, Aloe vera and Allium ampeloprasum, 1 gram BID, and diet based on ITM contains avoid of spicy foods is recommended for 4 weeks

Category

Treatment - Drugs

2

Description

Control group: diltigel, 1 gram BID and high fiber diet is recommended for 4 weeks .

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinics affiliated to Isfahan University of Medical Sciences

Full name of responsible person

Dr. Azam Teymuri

Street address

Isfahan University of Medical Sciences

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street

City

Mashhad

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, Mashhad 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**

Mashhad University of Medical Sciences

Full name of responsible person

Sedigheh Taavakoli Dastjerdi

Position

PhD Student of Traditional Medicine

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

Faculty of Iranian Traditional Medicine and Complementary, Opposite the Mehran Sports Hall, East Razi Ave

City

Mashhad

Postal code**Phone****Fax**

+98 51 3841 1538

Email

tavakkolis901@mums.c.ir

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Malihe Motavasselian

Position

Assistant Professor

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

Faculty of Iranian Traditional Medicine and Complementary, Opposite the Mehran Sports Hall, East Razi Ave

City

Mshhad

Postal code**Phone**

+98 51 3855 2188

Fax**Email**

motavasselianm@mums.ac.ir

Web page address

Person responsible for updating data

Contact**Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Sedigheh Tavkoli Dastjerdi

Position

phD student of Iranian Traditional Medicine

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

Faculty of Iranian Traditional Medicine and Complementary, Opposite the Mehran Sports Hall, East Razi Ave

City

Mashhad

Postal code**Phone**

+98 51 3855 2188

Fax

+98 51 3853 5980

Email

tavakkolis901@mums.ac.ir

Web page address

tavakkolis901@mums.ac.ir

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