

# 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

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## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

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**Full name of responsible person**

Malihe Motavasselian

**Position**

Assistant Professor

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## Person responsible for updating data

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phD student of Iranian Traditional Medicine

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## 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*