

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparison the therapeutic effect of traditional preparation compounded from Wallflower and Damask Rose flowers with the therapeutic effect of anti-fissure cream on anal fissure healings in patients having age of 20-50 years.

Protocol summary

Summary

The aim of this study is to evaluate the therapeutic effect of a traditional medicine containing Wallflower and Damask rose in anal fissure. Patients in the age range of 20 to 50, who have acute anal fissure with approval of a colorectal specialist are included in the study. The main exclusion criteria are other anorectal diseases (ex. fistula or anal cancer and hemorrhoids), pregnancy and lactation. Patients are divided into three groups of 30 patients: traditional medicine group, positive control group with conventional medication and placebo group. The medication in all three groups is taking a topical ointment for two weeks, twice a day, each time 0.5 g and up to 0.5 cm inside the anus. wound healing and pain relief is evaluated according to the specialist examination and results gathered from the checklist.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016121431406N1**
Registration date: **2017-01-16, 1395/10/27**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-01-16, 1395/10/27

Registrant information

Name

Ghazaleh Mosleh

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 3235 5677

Email address

moslehgh@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2017-02-19, 1395/12/01

Expected recruitment end date

2018-06-22, 1397/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the therapeutic effect of traditional preparation compounded from Wallflower and Damask Rose flowers with the therapeutic effect of anti-fissure cream on anal fissure healings in patients having age of 20-50 years.

Public title

The therapeutic effects of a topical preparation from Wallflower and Damask Rose on anal fissure.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: The expert diagnosis of anal fissure; willingness of patient to cooperate in the project; age of 20-50 years; lack of sensitivity to drug ingredients.

Exclusion criteria: Crohn's disease; fistula in the anal area; anal cancer; cardiovascular disorders; hemorrhoids; pregnancy and lactation; patients who consume blood pressure drugs; calcium channel blockers or nitrates; patients with a history of chronic headache; renal failure; HIV; tuberculosis; taking drugs such as heparin or aspirin and certain diseases such as thyroid problems.

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Committee of Research Ethics, Shiraz University of Medical Sciences

Street address

Shiraz University of Medical Sciences

City

Shiraz

Postal code

Approval date

2016-11-27, 1395/09/07

Ethics committee reference number

IR.SUMS.REC.1395.150

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

local wound healing

Timepoint

Before taking the drug, after a time period of two weeks and 4-6 weeks after drug is used

Method of measurement

visual scales of wounds

2

Description

Pain relief

Timepoint

Before taking the drug, after a time period of two weeks and 4-6 weeks after drug is used

Method of measurement

Quastionary of pain score

Secondary outcomes

1

Description

Improve quality of life

Timepoint

During and after the course of treatment

Method of measurement

quality of life questionnaire

2

Description

internal anal sphincter pressure

Timepoint

after the consumption of cerate

Method of measurement

manometry

Intervention groups

1

Description

Patients with acute anal fissure in positive control group with conventional medication. which is administered as a rectal ointment for two weeks, twice a day, each time a tip of the finger (0.5 g)

Category

Treatment - Drugs

2

Description

Patients with acute anal fissure in traditional drug group (cerate supplies of rose oil and wallflower oil and beeswax) which is administered as a rectal ointment for

two weeks, twice a day, each time a tip of the finger (0.5 g)

Category

Treatment - Drugs

3

Description

Patients with acute anal fissure in placebo group: a simple cerate base (cerate of sesame oil and wax) which is administered as a rectal ointment for two weeks, twice a day, each time a tip of the finger (0.5 g).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Faghihi clinic, colo-rectal research center

Full name of responsible person

Dr Seyed Vahid Hosseini

Street address

Colo-rectal research center, number 1 building,
Shahid Dr Faghihi hospital, Zand street, Shiraz

City

shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr Seyed Basir Hashemi, Vice Chancellor of Research

Street address

Vice-Chancellor for Research, 7th floor, Shiraz
University of Medical Sciences, next to the Red
Crescent center, Zand Blvd., Shiraz

City

Shiraz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shiraz 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

Faculty of pharmacy

Full name of responsible person

Ghazaleh Mosleh

Position

PhD student, traditional pharmacy

Other areas of specialty/work

Street address

Faculty of pharmacy

City

Shiraz

Postal code

Phone

+98 71 3235 5677

Fax

Email

moslehgh@sums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Faculty of pharmacy

Full name of responsible person

Prof. Abdolali Mohagheghzadeh

Position

Prof. in pharmacognosy

Other areas of specialty/work

Street address

Faculty of pharmacy, the head of traditional pharmacy
department

City

Shiraz

Postal code

Phone

+98 71 3635 0903

Fax

Email

mohaghegh@sums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Faculty of pharmacy

Full name of responsible person

Ghazaleh Mosleh

Position

PhD student, traditional pharmacy

Other areas of specialty/work

Street address

Faculty of pharmacy

City

Shiraz

Postal code
Phone
00
Fax
Email
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