

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Sep 2026

Double blind randomized placebo-control trial of Allium ampeloprasum cream effect for the management of hemorrhoids symptoms

Protocol summary

Summary

Purpose of study: evaluation of Allium ampeloprasum cream efficacy for the management of hemorrhoids
study design: Double blind randomized placebo-control trial, uni-central
Study population: Participants having symptomatic hemorrhoids attending Shiraz University of Medical Sciences clinics
Inclusion criteria: Patients with symptomatic hemorrhoids (GRADE 1-4) without need to emergency operation according to physical examination
Exclusion criteria: Participants having anal fissure or inflammatory bowel disease or history of gastrointestinal cancer
Sample size: 75 patients (three groups)
Interventions: Topical Allium ampeloprasum cream/ placebo cream/ anti-hemorrhoid cream
Time period: 3 week
Outcome measures: pain, itching, bleeding, defecate discomfort, total improvement, constipation

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014010816143N1**

Registration date: **2014-09-29, 1393/07/07**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-09-29, 1393/07/07

Registrant information

Name

Seyed Hamdollah Mosavat

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 3233 7589

Email address

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Recruitment status

Recruitment complete

Funding source

Research center for Traditional Medicine and History of Medicine Shiraz University of Medical Sciences

Expected recruitment start date

2014-09-24, 1393/07/02

Expected recruitment end date

2014-11-23, 1393/09/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Double blind randomized placebo-control trial of Allium ampeloprasum cream effect for the management of hemorrhoids symptoms

Public title

Evaluation of Allium ampeloprasum cream effect for the management of hemorrhoids symptoms

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: 1- Age: 18 Years to 65 Years 2- Participants who agree to participate in the current study 3- Participants having symptomatic hemorrhoids (GRADE 1-4) without need to emergency operation according to physical examination 4- Participants who do not use drugs other than the study drug and the control drug to treat their hemorrhoids during the study period.
exclusion criteria: 1- Participants having anal fissure or inflammatory bowel disease or history of gastrointestinal cancer 2- Participants having hypersensitive

predisposition or hypersensitive to Allium ampeloprasum or history of skin hypersensitivity 3- Female participants under pregnancy or during breastfeeding period 4- Participants complicated by serious cardio cerebro vascular diseases, hepatic and renal diseases, diseases of hemopoietic system or neurologic disorders or ascitis g- history of steroid or anticoagulant drug consumption

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **75**

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

Shiraz University of Medical Sciences

Street address

Vice-Chancellery of Research and Technology office,
Shiraz University of Medical Sciences, Zand street.

City

Shiraz

Postal code

Approval date

2014-08-24, 1393/06/02

Ethics committee reference number

CT-9377-7127

Health conditions studied

1

Description of health condition studied

hemorrhoids

ICD-10 code

I84.8

ICD-10 code description

Unspecified haemorrhoids with other complications

Primary outcomes

1

Description

pain

Timepoint

3 weeks after intervention

Method of measurement

visual analogue scale

2

Description

bleeding

Timepoint

3 weeks after intervention

Method of measurement

questionare

3

Description

itching

Timepoint

3 weeks after intervention

Method of measurement

questionare

4

Description

deficate discomfort

Timepoint

3 weeks after intervention

Method of measurement

visual analogue scale

5

Description

total improvment

Timepoint

3 weeks after intervention

Method of measurement

visual analogue scale

Secondary outcomes

1

Description

constipation

Timepoint

3 weeks after intervention

Method of measurement

questionare

Intervention groups

1

Description

Allium Ampleoprasum topical cream 1 cc twice daily for 3 weeks for intervention group

Category

Treatment - Drugs

2

Description

placebo topical cream 1 cc twice daily for 3 weeks for control group

Category

Treatment - Drugs

3

Description

Anti hemorrhoid topical cream 1 cc twice daily for 3 weeks for standard treatment group

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Motahari polyclinic

Full name of responsible person

Seyed Hamdollah Mosavat

Street address

nemazi square

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr.Gholamreza Haatam

Street address

Vice-Chancellery of Research and Technology, Shiraz University of Medical Sciences, Zand Street.

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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

Shiraz University of Medical Sciences

Full name of responsible person

Seyed Hamdollah Mosavat

Position

MD, PhD Candidate of Iranian Traditional Medicine

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Colorectal research center of Shiraz University of Medical Sciences

Full name of responsible person

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general surgun, fellowship of colorectal

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Person responsible for updating data

Contact

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Shiraz University of Medical Sciences

Full name of responsible person

Dr. Seyed Hamdollah Mosavat

Position

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

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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