

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Evaluation of the efficacy of rectal preparation from Hemoheal® Cream on number of excretion daily and rate of rectal bleeding in patients with Hemorrhoid

Protocol summary

Study aim

The goal of this randomized double blind placebo controlled clinical trial is to prescribe a Hemoheal cream for patients with Hemorrhoid and evaluation of the efficacy of this natural remedy. Compounds of Hemoheal cream are a rectal preparation for hemorrhoid which includes aqueous extract of *Allium schoenoprasum* L, *Commiphora Mukul* and *Sesamum Indicum* L, are being prepared by a traditional pharmacy of the Traditional Medicine Clinic of the Faculty of Traditional Medicine of Tehran University of Medical Sciences.

Design

40 patients will be treated randomly with either Hemoheal cream (intervention) or placebo (control) twice a day for 30 days. Each time, 1 thin layer of cream is put on the stance.

Settings and conduct

This study is done in Imam Reza hospital of Kermanshah University of Medical Sciences. Blinding is done for patients and physician who measure the outcome of the study. Randomization is performed using blocking method.

Participants/Inclusion and exclusion criteria

Major inclusion criteria include: age>18; patients who sign the testimonials and cooperate during the study and patients who were not cured with Hemoheal cream during the last month, and main exclusion criteria include: 4th-degree hemorrhoids; Pregnant patients and nursing mothers; Patients who have to use other drugs that interfere with this medication.

Intervention groups

Intervention: Topical use of thin-layer Hemoheal cream twice a day for a month
Control: Topical use of thin-layer eucerin base cream twice a day for a month

Main outcome variables

the number of excretion daily and rate of rectal bleeding are primary outcome measures, and gastrointestinal

disorders are secondary outcome measure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT2017091335460N1**

Registration date: **2017-09-13, 1396/06/22**

Registration timing: **prospective**

Last update: **2017-12-20, 1396/09/29**

Update count: **1**

Registration date

2017-09-13, 1396/06/22

Registrant information

Name

Fateme Parvizi

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 83 3429 9220

Email address

fatemeparvizi4@gmail.com

Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Sciences

Expected recruitment start date

2017-10-12, 1396/07/20

Expected recruitment end date

2018-01-10, 1396/10/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the efficacy of rectal preparation from Hemoheal® Cream on number of excretion daily and rate of rectal bleeding in patients with Hemorrhoid

Public title

Evaluation of the efficacy of rectal preparation from Hemoheal® Cream in patients with Hemorrhoid

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age>18 Patients who sign the testimonials and cooperate during the study Patients who their diseases are confirmed by complete medical evaluation including colonoscopy, pathology and laboratory data Only patients with mild to moderate hemorrhoids can be included in this study Patients who were not cured with Hemoheal cream during the last month

Exclusion criteria:

4th-degree hemorrhoids Pregnant patients and nursing mothers Patients who have to use other drugs that interference with this medication Previous history of anorectal surgery Patients who are suffering from other diseases in addition to hemorrhoids, such as apparent coagulation abnormalities or kidney impairment accompanied with colorectal diseases such as cancer, Crohn's disease, ulcerative colitis, anal fistula, anal fissure, proctitis or perineal skin inflammation Patients who are disposed to a serious health danger, such as severe cardiac, liver or renal diseases If significant side effects occur, the patient will be excluded from the study and followed to end of the study Patients with severe allergy to this plant (dermatitis contact)

AgeFrom **18 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample sizeTarget sample size: **40****Randomization (investigator's opinion)**

Randomized

Randomization description

Randomization is performed using blocking method.

Blinding (investigator's opinion)

Double blinded

Blinding description

Blinding is done for patients and physician who measure the outcome of the study.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Kermanshah University of Medical Sciences

Street address

Kermanshah University of Medical Sciences

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kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2017-10-25, 1396/08/03

Ethics committee reference number

IR.KUMS.REC.1396.391

Health conditions studied**1****Description of health condition studied**

Hemorroid

ICD-10 code

I84.8

ICD-10 code description

Unspecified haemorrhoids with other complications

Primary outcomes**1****Description**

Number of excretion daily

Timepoint

Before using the drug; 2 weeks after using the drug-30 days after using the drugs

Method of measurement

Based on Hemorrhoid clinic questionnaire

2**Description**

Rate of rectal bleeding

Timepoint

before using the drug; 2 weeks after using the drug-30 days after using the drugs

Method of measurement

based on Hemorrhoid clinic score

Secondary outcomes

1

Description

Gastrointestinal disorders

Timepoint

Two weeks after using the drug; 30 days after using the drug

Method of measurement

Based on side effect questionnaire

Intervention groups

1

Description

Intervention: Topical use of thin-layer Hemoheal cream twice a day for a month

Category

Treatment - Drugs

2

Description

Control: Topical use of thin-layer eucerin base cream twice a day for a month

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Dr. Mohammad Hosein Farzaei

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Imam Reza Hospital, Parastar Blvd., Kermanshah

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Kermanshah University

of Medical Sciences

Full name of responsible person

Dr. Mohamad hosein Farzaee

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Kermanshah University of Medical Sciences, Faculty of pharmacy, Daneshgah Ave., Shahid Shiroodi Blv., Kermanshah

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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

Vice Chancellor for Research, Kermanshah University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Fateme Parvizi

Position

Investigator of Kermanshah University of Medical Sciences

Latest degree

Master

Other areas of specialty/work

Others

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available