

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of effect of topical honey on on symptoms of hemorrhoid and anal fissure in patients of surgery clinics of Semnan, Iran

Protocol summary

Summary

In this Randomized double-blind clinical trial study, patients with internal hemorrhoid or chronic anal fissure are divided in two groups. In case group patients apply a mixture of honey and Vaseline with ratio of 1:2 and in control group patients use Vaseline as placebo topically. The patients are asked to apply 1 to 2 gram of the ointments with applicators into the anal canal two times a day. They are followed for 10 days, and visited every 5 days. Severity of pain, pruritus and bleeding are evaluated during the course of trial.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013122615162N2**
Registration date: **2014-01-09, 1392/10/19**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-01-09, 1392/10/19

Registrant information

Name

Jafar Alavy Toussy

Name of organization / entity

Semnan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 23 1445 7244

Email address

drtoussy@sem-ums.ac.ir

Recruitment status

Recruitment complete

Funding source

Semnan University of Medical Sciences

Expected recruitment start date

2011-03-11, 1389/12/20

Expected recruitment end date

2014-03-11, 1392/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of effect of topical honey on on symptoms of hemorrhoid and anal fissure in patients of surgery clinics of Semnan, Iran

Public title

Effect of topical honey on on symptoms of hemorrhoid and anal fissure

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with chronic anal fissure (anal fissure that has not cured after 6-8 weeks), patients with internal hemorrhoid - Exclusion criteria: Patients who received any other medical treatment for these diseases in the week before the trial; patients with acute fissure; patients with external hemorrhoid; patients that need any other treatment for these diseases

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**
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
Semnan University of Medical Sciences ethics committee
Street address
Deputy of Research, Basij Boulevard
City
Semnan
Postal code
Approval date
2010-11-21, 1389/08/30
Ethics committee reference number
92/374021

Health conditions studied

1

Description of health condition studied

Chronic anal fissure
ICD-10 code
K60.1
ICD-10 code description
Chronic anal fissure

2

Description of health condition studied

Internal haemorrhoids without complication
ICD-10 code
I84.2
ICD-10 code description
Internal haemorrhoids without complication

Primary outcomes

1

Description
Severity of pain
Timepoint

Beginning of study, 5th day, End of study
Method of measurement
Numeric rating pain scale

2

Description
Pruritus
Timepoint
Beginning of study, 5th day, End of study
Method of measurement
Questionnaire

3

Description
Bleeding
Timepoint
Beginning of study, 5th day, End of study
Method of measurement
Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
In intervention group, mixture of honey and Vaseline with ratio of 1 to 2, 1 to 2 gr BD is applied by use of applicator through anal canal. The honey that is used is without wax with commercial mark of Mahram corporation (Iran).
Category
Treatment - Drugs

2

Description
In control group, Vaseline
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Surgery clinic of Amir-al-Momenin Hospital
Full name of responsible person
Dr Setareh Soltany
Street address
Surgery department, Koosar Hospital, Shahrak-e Golestan
City
Semnan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Dr Raheb Ghorbani

Street address

Deputy of Research, Basij Boulevard

City

Semnan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Semnan 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

Semnan University of Medical Sciences

Full name of responsible person

Dr Jafar Alavy Toussy

Position

Pathologist / Lecturer

Other areas of specialty/work

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Pathology department, Koosar Hospital, Shahrak-e Golestan

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Dr Setareh Soltany

Position

Surgeon / Associate professor

Other areas of specialty/work

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Person responsible for updating data

Contact

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Full name of responsible person

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Position

Pathologist / Lecturer

Other areas of specialty/work

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Web page address

<http://www.toussysoftware.com>

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