

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

The efficacy of herbal anti-hemorrhoid suppository containing essential oil of *Myrtus Communis* in reducing the severity of hemorrhoids and its complications

Protocol summary

Study aim

The comparative study of efficiency of herbal anti hemorrhoid suppository containing different doses of essential oil of *Myrtus Communis* and conventional anti hemorrhoid suppositor on Type 1 and 2 hemorrhoids symptoms

Design

Randomized clinical trial, controlled with medicine, parallel, double blind, single central

Settings and conduct

This study is a clinical trial on 180 patients with Type 1 and 2 hemorrhoids who do not need emergency surgery referred to research presenter office. Individuals based on table of random numbers will be divided to one of the groups received suppository containing 10% or 15% essential oil of *Myrtus Communis* or routine suppository BID for 2 weeks randomly . All drug are presented in the same package and the physician , patients, researcher and statistical analyst are blind .After analyzing data, codes will be decoded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All the visited patients with Type 1 and 2 hemorrhoids who do not need emergency surgery referred to research presenter office. Exclusion criteria: External thrombosed hemorrhoid; Internal strangulated hemorrhoid; Anal fistula; Anal fissure; Anal abscess; Pregnancy; Portal hypertension; Type 3 and 4 hemorrhoids; Renal insufficiency; Malignancies; pregnancy

Intervention groups

Intervention groups: herbal anti hemorrhoid suppository containing 10% , 15 %essential oil of *Myrtus Communis* , BID for two weeks. Control group: conventional anti hemorrhoid suppository, BID for two weeks

Main outcome variables

severity of hemorrhoid, bleeding, Pain during bowel movements

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130211012438N26**

Registration date: **2018-05-23, 1397/03/02**

Registration timing: **registered_while_recruiting**

Last update: **2018-05-23, 1397/03/02**

Update count: **0**

Registration date

2018-05-23, 1397/03/02

Registrant information

Name

Mohsen Taghizadeh

Name of organization / entity

Kashan University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-21, 1397/02/01

Expected recruitment end date

2018-09-23, 1397/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The efficacy of herbal anti-hemorrhoid suppository containing essential oil of Myrtus Communis in reducing the severity of hemorrhoids and its complications

Public title

The efficacy of Myrtus Communis suppository on hemorrhoids

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All the visited patients with Type1 and 2 hemorrhoids who do not need emergency surgery referred to presenter office

Exclusion criteria:

External thrombosed hemorrhoid Internal strangulated hemorrhoid Anal fistula Anal fissure Anal abscess Portal hypertension Type 3 and 4 hemorrhoids Renal insufficiency Malignancies Pregnancy

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **180**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomized based on table of random numbers

Blinding (investigator's opinion)

Double blinded

Blinding description

Coding and similar packaging. The physician, patient, researcher and statistical analyzer are blind. At the end of the study and analysis of data, codes are decoded.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kashan University of Medical Sciences

Street address

Kashan University Of Medical Sciences, Kashan

City

Kashan

Province

Isfahan

Postal code

81151-87159

Approval date

2016-11-16, 1395/08/26

Ethics committee reference number

IR.KAUMS.REC.1395.85

Health conditions studied

1

Description of health condition studied

hemorrhoids

ICD-10 code

K64

ICD-10 code description

Hemorrhoids and perianal venous thrombosis

Primary outcomes

1

Description

bleeding

Timepoint

Before intervention, 2 weeks after the initial intervention

Method of measurement

questionnaire

2

Description

Pain during bowel movements

Timepoint

Before intervention, 2 weeks after initiation of intervention

Method of measurement

questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: herbal anti hemorrhoid suppository containing 10% essential oil of Myrtus Communis,

prepared in the formulation unit of Barij Essence
Pharmaceutical Company , BID for two weeks

Category

Treatment - Drugs

2**Description**

Intervention group: herbal anti hemorrhoid suppository
containing 15 %essential oil of Myrtus Communis,
prepared in the formulation unit of Barij Essence
Pharmaceutical Company , BID for two weeks

Category

Treatment - Drugs

3**Description**

Control group:conventional anti hemorrhoid suppository,
prepared in the formulation unit of Barij Essence
Pharmaceutical Company, BID for two weeks

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

research presenter office

Full name of responsible person

DR Mohammad Eidy

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Barij Research Center of Medicinal Herbs

Full name of responsible person

Miss L.Hejazi

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Web page address

http://www.barijessence.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Barij Research Center of Medicinal Herbs

Proportion provided by this source

50

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

2**Sponsor****Name of organization / entity**

Kashan University of Medical Sciences

Full name of responsible person

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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

Kashan University of Medical Sciences

Proportion provided by this source

50

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
Kashan University of Medical Sciences
Full name of responsible person
M.Taghizadeh
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phd
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Person responsible for updating data

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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

Undecided - It is not yet known if there will be 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