Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 onType 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 Type1 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 Type1 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
Iran (Islamic Republic of)

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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
Isfehan

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 containing15 %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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Vali Asr Medical Building, Shahid Beheshti St, Kashan

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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

Street address

Kashan Mashhad Ardehal Road, KM44

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Email

info@barijessence.com

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

Dr Gholam Ali Hamidi

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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

Position

phd

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Mohammad Eidy

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

General Surgery

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Person responsible for updating data

Contact

Name of organization / entity

Barij Essence Research Center of Medicinal Herbs

Full name of responsible person

Mahlouji Mahnaz

Position

Expert in clinical research

Latest degree

Bachelor

Other areas of specialty/work

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Web page address

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