

# 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 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)

##### Phone

+98 36 1555 0021

##### Email address

taghizadeh\_m@kaums.ac.ir

##### 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

**Street address**

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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**Province**

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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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**Web page address**

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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 scientific inquiries

### Contact

**Name of organization / entity**  
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Assistant Professor  
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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  
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Expert in clinical research  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Midwifery  
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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