

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 2026

### Formulation, physicochemical evaluation and comparison of the effect of ointment prepared from *Myrtus communis* L. and *Colchicum autumnale* L. with anti-hemorrhoid ointment on the symptoms of grade I and II internal hemorrhoids: a three-blind controlled clinical trial

#### Protocol summary

##### Study aim

Comparison of the effect of ointment prepared from Myrtle and wild-saffron medicinal plants with anti-hemorrhoid ointment on the symptoms of grade I and II internal hemorrhoids.

##### Design

This three-blind randomized clinical trial will be conducted on 60 men and women with grade I and II hemorrhoids.

##### Settings and conduct

Patients referred to Tabriz medical centers will be assigned to two intervention and control groups using random block design. The intervention group will receive herbal ointment and the control will receive anti-hemorrhoid ointment twice a day for 4 week. With the colorectal clinical evaluation questionnaire, the amount of pain, itching, swelling, bleeding, anal discomfort and the negative effect of hemorrhoids on people's sense of health and well-being will be investigated.

##### Participants/Inclusion and exclusion criteria

Entry requirements; Patients in the age group of 17 to 70, literate and suffering from 1 and 2 degree hemorrhoids Non-entry condition; Use of systemic steroidal and non-steroidal anti-inflammatory drugs and analgesic treatments; and anti hemorrhoid (for one month before the study) and the use of anticoagulant drugs; The need for surgery to treat hemorrhoids Suffering from inflammatory infectious diseases of the digestive tract or colorectal cancer; Previous use of laser or use of phlebotonic drug to treat hemorrhoids one week before from entering the study or participating in another interventional study

##### Intervention groups

The people of the intervention group, including 60 men and women with first and second degree hemorrhoids, will receive herbal ointment. Also, the control group will

include 60 men and women with first and second grade hemorrhoids, who will receive anti-hemorrhoid ointment.

##### Main outcome variables

formulation of anti-hemorrhoid ointment Determining the effect of this ointment on the symptoms of grade I and II internal hemorrhoids

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20221013056160N1**

Registration date: **2022-12-18, 1401/09/27**

Registration timing: **prospective**

Last update: **2022-12-18, 1401/09/27**

Update count: **0**

##### Registration date

2022-12-18, 1401/09/27

##### Registrant information

##### Name

Negar Valizadeh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

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##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-01-11, 1401/10/21  
**Expected recruitment end date**  
2023-09-22, 1402/06/31  
**Actual recruitment start date**  
empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

**Scientific title**  
Formulation, physicochemical evaluation and comparison of the effect of ointment prepared from Myrtus communis L. and Colchicum autumnale L. with anti-hemorrhoid ointment on the symptoms of grade I and II internal hemorrhoids: a three-blind controlled clinical trial

**Public title**  
Investigating the effect of ointment prepared from Myrtus communis L. and Colchicum autumnale L. for the treatment of grade I and II internal hemorrhoids

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Clients with first and second grade hemorrhoids who have been diagnosed with clinical symptoms and confirmation from a general surgeon. Patients should be in the age group of 17 to 70 years. Hemorrhoids of the clients are not caused by systemic diseases such as hypertension. Presence of hemorrhoid symptoms for at least more than 6 days Ability to read and write

**Exclusion criteria:**

Use of systemic steroidal and non-steroidal anti-inflammatory drugs and analgesic treatments The use of systemic steroidal and non-steroidal anti-inflammatory drugs and analgesic and anti-hemorrhoid treatments (for one month before the study) and the use of anticoagulant drugs. The need for a surgical method to treat hemorrhoids (with the approval of a gastroenterologist and using clinical and colonoscopy tests) Patients with problems such as anorectal abscess, fistula, tuberculosis, herpes, varicella (confirmed by clinical tests or colonoscopy) Infectious inflammatory diseases of the digestive tract or colorectal cancer (according to the patient's statement) Previous use of laser or use of phlebotonic medicine to treat hemorrhoids one week before entering the study (according to the patient's statement) Participation in another interventional study

**Age**  
From **17 years** old to **70 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Participant
- Care provider
- Investigator

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Random allocation rule This method represents a large block for the entire sample volume, which means that the balance in the number of people It will be allocated to each of the groups at the end of the study. For this purpose, he first determined a total sample size, then randomly assigned a group of them to group A and the rest to group B.

**Blinding (investigator's opinion)**

Triple blinded

**Blinding description**

This three-blind randomized clinical trial will be conducted on 60 men and women with grade I and II hemorrhoids referring to health and treatment centers in Tabriz city. Eligible people will be assigned to two intervention and control groups using random block. In this study, the researcher, participant and clinical caregiver will not know the type of intervention received by the participants.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Ethics committee of TABriz University of Medical Sciences

**Street address**

Tabriz University, Building No. 2 of Medical Sciences, Research and Technology Vice-Chancellor, 3rd floor

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

۵۱۶۶۶۱۶۴۷۱

**Approval date**

2022-09-12, 1401/06/21

**Ethics committee reference number**

IR.TBZMED.REC.1401.516

**Health conditions studied**

**1**

**Description of health condition studied**

grade I and II internal hemorrhoids

**ICD-10 code**

## ICD-10 code description

### Primary outcomes

#### 1

##### Description

Investigating the amount of pain with the colo-rectal clinical treatment evaluation questionnaire

##### Timepoint

This questionnaire will be completed once before the start of the study and then in the first, second and fourth weeks, and once after the end of the intervention, in the eighth week after the start of the treatment.

##### Method of measurement

(CORECTS= Colo-Rectal Evaluation of Clinical Therapeutics Scale)

#### 2

##### Description

Investigating the amount of itching around the anus with the colorectal clinical treatment evaluation questionnaire

##### Timepoint

This questionnaire will be completed once before the start of the study and then in the first, second and fourth weeks, and once after the end of the intervention, in the eighth week after the start of the treatment.

##### Method of measurement

(CORECTS= Colo-Rectal Evaluation of Clinical Therapeutics Scale)

#### 3

##### Description

Investigating the amount of bleeding with the colo-rectal clinical treatment evaluation questionnaire

##### Timepoint

This questionnaire will be completed once before the start of the study and then in the first, second and fourth weeks, and once after the end of the intervention, in the eighth week after the start of the treatment.

##### Method of measurement

(CORECTS= Colo-Rectal Evaluation of Clinical Therapeutics Scale)

### Secondary outcomes

#### 1

##### Description

The questionnaire (WHOQOL-BREF) will be used to measure the quality of life

##### Timepoint

This questionnaire will be completed before the start of the study, in the fourth week after the intervention and in the eighth week after the start of the treatment.

##### Method of measurement

Questionnaire (WHOQOL-BREF)

### Intervention groups

#### 1

##### Description

Intervention group: Intervention group: The intervention group includes 60 men and women with first and second degree hemorrhoids, referring to medical centers in Tabriz city, who will receive the herbal ointment.

##### Category

Treatment - Drugs

#### 2

##### Description

Control group: The control group will include 60 men and women with first and second grade hemorrhoids in the same centers that will receive anti-hemorrhoid ointment or suppositories.

##### Category

Treatment - Drugs

### Recruitment centers

#### 1

##### Recruitment center

###### Name of recruitment center

Imam Sajjad Hospital

###### Full name of responsible person

Babak Abri Aghdam

###### Street address

East side of Pasdaran highway, Educational complex of Islamic Azad University of Tabriz, Imam Sajjad Hospital, Tabriz, Iran

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#### 2

##### Recruitment center

###### Name of recruitment center

Amiralmomenin Hospital

###### Full name of responsible person

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###### Street address

Above Mantash station, Quds St., Amiralmomenin Hospital, Tabriz, Iran

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5137844787  
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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Applied Pharmaceutical Research Center, Tabriz  
University of Medical Sciences  
**Full name of responsible person**  
Hamed Hamishehkar  
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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

Applied Pharmaceutical Research Center, Tabriz  
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**  
Tabriz University of Medical Sciences  
**Full name of responsible person**  
Babak Abri Aghdam

**Position**  
Assistant professor  
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**Other areas of specialty/work**  
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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
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## Person responsible for updating data

#### Contact

**Name of organization / entity**  
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**Full name of responsible person**  
Hamed Hamishehkar  
**Position**

Associate professor

**Latest degree**

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**Other areas of specialty/work**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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**

Yes - There is 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

**Title and more details about the data/document**

All data is potentially shareable after de-identifying individuals

**When the data will become available and for how long**

The access period starts 12 months after the results are published

**To whom data/document is available**

Academic and scientific institutions

**Under which criteria data/document could be used**

Mentioning the source should be used in all stages of their research and writing the article.

**From where data/document is obtainable**

Dr. Hamed Hamishehkar Associate Professor of Faculty of Pharmacy in Tabriz Mobile phone: 00989143169252

Email: hamishehkar.hamed@gmail.com

**What processes are involved for a request to access data/document**

Immediately after the request, the effect will be arranged.

**Comments**