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 automnale 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 phlebutonic 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)

Phone

+98 41 3330 7795

Email address

n.valizadeh@rifr-ac.ir

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 automnale 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 automnale 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
City
Tabriz
Province
East Azarbaijan
Postal code
5157944533
Phone
+98 41 3196 6000
Email
info@iaut.ac.ir
Web page address
https://tabriz.iau.ir/fa

2

Recruitment center
Name of recruitment center
Amiralmoemenin Hospital
Full name of responsible person
Babak Abri Aghdam
Street address
Above Mantash station,Quds St., Amiralmoemenin Hospital,Tabriz, iran
City
Tabriz
Province
East Azarbaijan

Postal code
5137844787
Phone
+98 41 9101 0920
Email
hospital.ali1@gmail.com
Web page address
http://alihospital.ir/

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
Street address
University Street, Research and Development Complex of Tabriz University of Medical Sciences, Applied Pharmaceutical Research Center, Tabriz, Iran.
City
Tabriz
Province
East Azarbaijan
Postal code
0000000000
Phone
+98 41 3335 7314
Email
info.medfac@tbzmed.ac.ir
Web page address
https://medfac.tbzmed.ac.ir/
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
Latest degree
Subspecialist
Other areas of specialty/work
General Surgery
Street address
Unit D, 5th Floor, Hakim Building, , Between Shariati and Taleghani Intersection, , Pastor New Street, Tabriz, Iran.
City
Tabriz
Province
East Azarbaijan
Postal code
0000000000
Phone
+98 41 3557 3306
Email
babak756a@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Hamed Hamishehkar
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Medical Pharmacy
Street address
Applied Pharmaceutical Research Center, Tabriz University of Medical Sciences, University Street, Tabriz.
City
Tabriz
Province
East Azarbaijan
Postal code
0000000000
Phone
+98 41 3336 3311
Fax
+98 41 3336 3231
Email
hamishehkar.hamed@gmail.com
Web page address
https://darc-fa.tbzmed.ac.ir/?PageID=31

Person responsible for updating data

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Hamed Hamishehkar
Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

Street address

Applied Pharmaceutical Research Center, Tabriz University of Medical Sciences, University Street, Tabriz.

City

Tabriz

Province

East Azarbaijan

Postal code

5165665811

Phone

+98 41 3337 8163

Fax

+98 41 3336 3231

Email

hamishehkar.hamed@gmail.com

Web page address

https://darc-fa.tbzmed.ac.ir/

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