Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jun 2026

Study of therapeutic effects of ointment containing hydro alcoholic extract of root and rhizome of Ruscus hyrcanus woronow in patients with chronic venous insufficiency (Grade 1 and 2 hemorrhoids); a randomized, double blind, controlled with placebo study.

Protocol summary

Study aim
Preparation of hydroalcoholic extract of Ruscus hyrcanus ointment and evaluation of therapeutic effect in chronic venous insufficiency (hemorrhoid).

Design
Randomized trial by pseudo random numbers table, double blind with parallel control and intervention groups. Each group contains 30 members.

Settings and conduct
Topical hemorrhoid treatment in patients referring to Razi Hospital in Gaemshahr and Imam Khomeini in Sari, researcher, participant, clinical caregiver and outcome evaluator are blinded in this trial.

Participants/Inclusion and exclusion criteria
Patients older than 18 years with first and second degree hemorrhoids are enrolled. Patients with a history of allergic reactions to the plants of Asparagaceae family; pregnant or breastfeeding; with a history of anorectal surgery or any non-medical treatment of hemorrhoids or any malignancy Will not enter the study.

Intervention groups
Intervention group receive Ruscus extract 2% ointment BD in amount of 1 cm for one month. The control group receive placebo ointment in the same way.

Main outcome variables
The amount of permanent pain, pain during defecation, anal bleeding, burning and itching, unpleasantness and amount of strain during defecation are the main consequences.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100107003014N20**

Registration date: **2018-10-28, 1397/08/06**

Registration timing: **registered_while_recruiting**

Last update: **2018-10-28, 1397/08/06**

Update count: **0**

Registration date

2018-10-28, 1397/08/06

Registrant information

Name
Shahram Ala

Name of organization / entity
Mazandaran University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-11, 1397/06/20

Expected recruitment end date

2018-11-21, 1397/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of therapeutic effects of ointment containing hydro alcoholic extract of root and rhizome of Ruscus hyrcanus

woronow in patients with chronic venous insufficiency (Grade 1 and 2 hemorrhoids); a randomized, double blind, controlled with placebo study.

Public title
Effect of hydroalcoholic extract of Ruscus hyrcanus in treatment of chronic venous insufficiency
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
at least 18 years old first and second untreated hemorrhoids
Exclusion criteria:
History of allergic reactions to plants in this family Pregnancy and Lactation History of any anorectal surgery and non-pharmacological treatment of hemorrhoids Ascetic, IBD, Inflammation and any illness that causes rectal bleeding Thrombosis or external hypersensitivity of the hemorrhoid Fissure or anal fistula Hemorrhoids Grade 3 and 4 Anal abscess, port hypertension Renal failure and any malignancy
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization is done through a random number table.
Blinding (investigator's opinion)
Double blinded
Blinding description
Ointments made in "placebo" and "Drug" groups, are numbered in the list by the supervisor. After prescribing by the physician, the code of prescribed ointment will be entered into the questionnaire. Physician, Patient and investigator are not aware of the type of ointment.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mazandaran University of Medical
Street address
moalem sq.vice chancelor of research, MAZUMS
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Sari
Province
Mazandaran
Postal code
33971- 48157
Approval date
2018-06-21, 1397/03/31
Ethics committee reference number
IR.Mazums.Rec.1397.1573

Health conditions studied

1

Description of health condition studied
Hemorrhoids grade 1
ICD-10 code
K64.0
ICD-10 code description
First degree hemorrhoids

2

Description of health condition studied
Hemorrhoids grade 2
ICD-10 code
K64.1
ICD-10 code description
Second degree hemorrhoids

Primary outcomes

1

Description
Permanent pain
Timepoint
Measuring the amount of pain at the beginning of the study, the first week, the second, third and fourth weeks after the start of the study, is evaluated and recorded.
Method of measurement
Visual Analogue Scale

2

Description
Pain during defecation
Timepoint
Measuring the amount of pain at the beginning of the study, the first week, the second, third and fourth weeks after the start of the study, is evaluated and recorded.
Method of measurement
Visual analogue Scale

3

Description
Anal bleeding
Timepoint
Measuring the amount of bleeding at the beginning of the study, the first week, the second, third and fourth weeks after the start of the study, is evaluated and recorded.
Method of measurement
Visually and classified as: bloodless (0), low (1), moderate (2) and high (3)

4

Description
strain during defecation
Timepoint
Measuring the amount of strain at the beginning of the study, the first week, the second, third and fourth weeks after the start of the study, is evaluated and recorded.
Method of measurement
Mental scaling: defecation without strain(0), low(1), intermediate(2), high (3)

5

Description
Burning and itchy and unpleasant
Timepoint
Measuring the amount of Burning and itching at the beginning of the study, the first week, the second, third and fourth weeks after the start of the study, is evaluated and recorded.
Method of measurement
Visual analogue Scale

Secondary outcomes

1

Description
Side effect during treatment
Timepoint
The type of side effect measured during treatment at the first, second, third and fourth week after the start of treatment.
Method of measurement
observation and according to questionnaire

Intervention groups

1

Description
Intervention group: Ruscus extract 2% ointment/ 2 times daily/ 1 cm of the ointment/ For one month
Category
Treatment - Drugs

2

Description
Control group: ointment formolation without any drugs/ 1 cm of the ointment/ For one month
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital of Sari
Full name of responsible person
Dr Shahram Ala
Street address
Imam Khomeini Hospital, Amir-Mazandarani street, Sari, Mazandaran, Iran
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2

Recruitment center
Name of recruitment center
Razi hospital and educational center
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3

Recruitment center
Name of recruitment center
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Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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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
Vice chancellor for research and technology, Mazandaran 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
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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

Not applicable

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