

# 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 15 1354 3083

##### Email address

sala@mazums.ac.ir

#### 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*

worow 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

###### City

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 formulation 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

##### **City**

Sari

##### **Province**

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4815733971

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+98 11 3354 3083

##### **Email**

sala@mazums.ac.ir

### 2

#### **Recruitment center**

##### **Name of recruitment center**

Razi hospital and educational center

##### **Full name of responsible person**

Dr. Shahram Ala

##### **Street address**

Payambar azam University Complex, Mazandaran University of Medical Sciences, Faculty of Pharmacy, Km 20 Khazar abad Road

##### **City**

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##### **Province**

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##### **Postal code**

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##### **Email**

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### 3

#### **Recruitment center**

##### **Name of recruitment center**

Dr Mina Alvandi Pour's office

##### **Full name of responsible person**

Dr. Mina Alvandipoor

##### **Street address**

Mazandaran Province, Sari, No. 21, Farhang Street, Iran

##### **City**

sari

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Mazandaran  
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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Vice chancellor for research and technology,  
Mazandaran University of Medical Sciences  
**Full name of responsible person**  
Dr. Shahram Ala  
**Street address**  
Payambar azam university complex, Mazandaran  
University of Medical Sciences, Faculty of pharmacy,  
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pajooheshi@mazums.ac.ir  
**Web page address**

#### 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

**Name of organization / entity**  
Mazandaran University of Medical Sciences  
**Full name of responsible person**  
Fateme Shamalizade Baii

**Position**  
Pharmacy student  
**Latest degree**  
A Level or less  
**Other areas of specialty/work**  
Medical Pharmacy  
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## Person responsible for scientific inquiries

#### Contact

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Mazandaran University of Medical Sciences  
**Full name of responsible person**  
Dr. Shahram Ala  
**Position**  
Professor  
**Latest degree**  
Specialist  
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## Person responsible for updating data

#### Contact

**Name of organization / entity**  
Mazandaran University of Medical Sciences  
**Full name of responsible person**  
Dr. Shahram Ala  
**Position**  
professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**

Medical Pharmacy

**Street address**

Payambar Azam University Complex, Mazandaran  
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**Email**

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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