

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 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 (Varicos vein); a randomized, double blind, controlled with placebo.

Protocol summary

Study aim

Study of therapeutic effects of ointment containing hydro alcoholic extract of root and rhizome of *Ruscus hyrcanus* woronow in patients with chronic venous insufficiency (Varicos vein)

Design

Randomized trial by pseudo random numbers table, double blind with parallel control and intervention groups.

Settings and conduct

Topical Varicose vein treatment In patients referring to Specialized clinic of Mostafavian and Dr. Davoudi's office. researcher, participant, clinical caregiver and outcome evaluator are blinded in this trial.

Participants/Inclusion and exclusion criteria

Patients over the age of 18 with asymptomatic lower limb varices vein are enrolled and patients with a history of allergic reaction to the plants of this family; pregnant or breastfeeding; and those with uncontrolled diabetes will not be included.

Intervention groups

Intervention group receive *Ruscus* extract 2% ointment 2 times daily in amount of 1 cm and For one month. The control group receive placebo ointment in the same way.

Main outcome variables

The amount of pain and feet heaviness; Changes in the amount of swollen ankles; Variation of vascular changes in vascular area according to questionnaire are the main consequences

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100107003014N21**

Registration date: **2018-12-06, 1397/09/15**

Registration timing: **registered_while_recruiting**

Last update: **2018-12-06, 1397/09/15**

Update count: **0**

Registration date

2018-12-06, 1397/09/15

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

2018-09-23, 1397/07/01

Expected recruitment end date

2019-02-20, 1397/12/01

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 (Varicos vein); a randomized, double blind, controlled with placebo.

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 varicose grade C1, C2 and C3

Exclusion criteria:

History of allergic reactions to plants in this family
Pregnancy and Lactation Uncontrolled Diabetes

Age

From **18 years** old

Gender

Both

Phase

0

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization by 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

48157-33971

Approval date

2018-06-21, 1397/03/31

Ethics committee reference number

IR.MAZUMS.Rec.1397.153

Health conditions studied

1

Description of health condition studied

Varicose vein of lower extremities

ICD-10 code

I83.9

ICD-10 code description

Asymptomatic varicose veins of lower extremities

Primary outcomes

1

Description

The amount of pain and feet heaviness according to the questionnaire.

Timepoint

Completion of the questionnaire and examination at the beginning of the study and 14 and 28 days after the start of the application of *Ruscus* ointment.

Method of measurement

Aberdeen varicose vein questionnaire (AVVQ),
Observation and examination

2

Description

Changes in the amount of swollen ankles according to the questionnaire.

Timepoint

Completion of the questionnaire and examination at the beginning of the study and 14 and 28 days after the start of the application of *Ruscus* ointment

Method of measurement

Aberdeen varicose vein questionnaire (AVVQ),
Observation and examination

3

Description

Variation of vascular changes in vascular area according to questionnaire.

Timepoint

Completion of the questionnaire and examination at the beginning of the study and 14 and 28 days after the start of the application of *Ruscus* ointment.

Method of measurement

Aberdeen varicose vein questionnaire (AVVQ),
Observation and examination

Secondary outcomes

empty

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

Specialized clinic of Mostafavian

Full name of responsible person

Dr.Shahram Ala

Street address

Payambar azam university complex, Mazandaran University of Medical Sciences, Faculty of pharmacy, Km 18 Khazar abad road, Sari, Mazandaran, Iran

City

Sari

Province

Mazandaran

Postal code

4815733971

Phone

+98 11 3325 7230

Email

Sala@mazums.ac.ir

2

Recruitment center

Name of recruitment center

Dr. Davoudi's office

Full name of responsible person

Dr. Shahram ala

Street address

Payambar azam university complex, Mazandaran University of Medical Sciences, Faculty of pharmacy, Km 18 Khazar abad road, Sari, Mazandaran, Iran

City

Sari

Province

Mazandaran

Postal code

4815733971

Phone

+98 11 3325 7230

Email

sala@mazums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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, Km 18 Khazar abad road, Sari, Mazandaran, Iran

City

Sari

Province

Mazandaran

Postal code

4815733971

Phone

+98 11 3325 7230

Email

pajooheshi@mazums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Sari 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

Ehsan seifi

Position

Pharmacy student

Latest degree

A Level or less

Other areas of specialty/work

Medical Pharmacy

Street address

Payambar azam university complex, Mazandaran

University of Medical Sciences, Faculty of pharmacy,
Km 18 Khazar abad road, Sari, Mazandaran, Iran

City

Sari

Province

Mazandaran

Postal code

4815733971

Phone

+98 11 3354 3083

Email

sala@mazums.ac.ir

Person responsible for scientific inquiries

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
University of Medical Sciences, Faculty of Pharmacy,
Km 18 Khazar Abad Road, Sari, Mazandaran, Iran

City

Sari

Province

Mazandaran

Postal code

4815733971

Phone

+98 11 3354 3083

Email

sala@mazums.ac.ir

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
University of Medical Sciences, Faculty of Pharmacy,
Km 18 Khazar Abad Road

City

sari

Province

Mazandaran

Postal code

4815733971

Phone

+98 11 3354 3083

Email

sala@mazums.ac.ir

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