

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effects of curcumin in people with chronic venous insufficiency on wound healing

Protocol summary

Study aim

Determining the effects of curcumin in patients with chronic venous insufficiency on wound healing in a double-blind clinical trial

Design

This study is a double-blind randomized clinical trial. Using the provincial hospital registry system at random, patients with chronic venous insufficiency are invited to participate in the present study if they wish. The researchers explained to the patients the purpose of the research and if they wish to enter the study, the informed consent form will be completed by the patients

Settings and conduct

Using the provincial hospital registry system at random, patients with chronic venous insufficiency are invited to participate in the present study if they wish. The patients admitted to the study will take 1 curcumin tablet per day at a dose of 500 mg and the control group will receive a placebo. After 6 weeks, the disease improvement criteria will be compared between the two groups. The raw material of placebo and curcumin is provided by Sami Labs LTD (Bangalore, India). Each 500 mg tablet of curcumin (which is a C3 complex), as well as each placebo tablet, contains 5 mg of piperine.

Participants/Inclusion and exclusion criteria

Inclusion criteria include all patients with chronic venous ulcers (clinical class 6 chronic venous insufficiency) and exclusion criteria include patient dissatisfaction and patient referral for follow-up and liver failure and the presence of biliary obstructive problems.

Intervention groups

Curcumin tablets 500 mg once daily for 6 weeks

Main outcome variables

Wound surface, reduction of edema, heaviness, and pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220404054408N1**

Registration date: **2022-08-18, 1401/05/27**

Registration timing: **registered_while_recruiting**

Last update: **2022-08-18, 1401/05/27**

Update count: **0**

Registration date

2022-08-18, 1401/05/27

Registrant information

Name

shirin saberianpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3841 2081

Email address

saberianpoursh@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-22, 1401/03/01

Expected recruitment end date

2022-08-23, 1401/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effects of curcumin in people with chronic venous insufficiency on wound healing

Public title

Evaluation of the effects of curcumin in people with chronic venous insufficiency

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Satisfaction with inclusion in the study Having an age range between 30 and 60 years Having chronic venous insufficiency class 3 and above

Exclusion criteria:

Having other vascular diseases Having diabetes Having autoimmune diseases

Age

From **30 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

Block The block randomization method is used so that blocks with size 4 are a combination of letters A and B. (ABBA, ABAB, AABB, BAAB, BBAA, BABA) The required number is selected using a table of random numbers and individuals are assigned to groups according to the created sequence.

Blinding (investigator's opinion)

Double blinded

Blinding description

The main tablets and placebo are exactly the same color and shape as the main tablets, so the participants can not understand the difference between the two.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mashhad university of medical science

Street address

Daneshgah street

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2022-02-16, 1400/11/27

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1401.002

Health conditions studied

1

Description of health condition studied

Chronic venous insufficiency

ICD-10 code

A52.0

ICD-10 code description

Cardiovascular and cerebrovascular syphilis

Primary outcomes

1

Description

Wound healing

Timepoint

6 weeks

Method of measurement

Wound length and width

2

Description

Reduce edema

Timepoint

6 weeks later

Method of measurement

Clinical examinations by a subspecialty physician and comparison with pre-interference

3

Description

Feeling of heaviness and pain

Timepoint

6 weeks later

Method of measurement

Clinical examinations by a subspecialty physician and comparison with pre-interference

Secondary outcomes

1

Description

Blood factors blood cell(WBC)PlateletD-dimer, Fibrinogen, Fibrinogen to albumin, ratioNeutrophil toLymphocyte ,Neutrophil, lymphocyte homocysteine

Timepoint

6 weeks later

Method of measurement

Laboratory techniques such as diagnostic kits

Intervention groups

1

Description

Intervention group: These patients are given tablets containing 500 mg of curcumin (C3 complex) from Sami Labs LTD (Bangalore, India) and 5 mg of piperine orally for 6 weeks.

Category

Treatment - Drugs

2

Description

Placebo tablets containing 5 mg of piperine, which are the same shape and color as the tablets of the intervention group, are given daily for 6 weeks and are provided by Sami Labs LTD (Bangalore, India).

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Velayat hospital

Full name of responsible person

Shirin Saberianpour

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Fakori bulvar

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saberianpoursh@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Majid Ghayour Mobarhan

Street address

Daneshgah bulvar

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948564

Phone

+98 51 3800 2288

Email

ghayourm@mums.ac.ir

Web page address

<https://v-research.mums.ac.ir/images/v-research/dr.ghayour1400>.

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Shirin Saberianpour

Position

Researcher

Latest degree

Ph.D.

Other areas of specialty/work

Medical Biotechnology

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Patient dissatisfaction

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Patient identity data is inaccessible but other data is accessible

When the data will become available and for how long

6 months to 1 year

To whom data/document is available

researchers

Under which criteria data/document could be used

For use in future research projects

From where data/document is obtainable

executor of plan

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

A process that is overseen by the Research Ethics Committee

Comments