Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

investigation and Comparison of the effect of Daflon and pentoxifylline in the treatment of patients with chronic venous insufficiency

Protocol summary

Study aim

Determining and comparing the effect of daflon and pentoxifylline on the clinical symptoms of chronic venous insufficiency

Design

Each patient will enter the study after checking the conditions of entering the study and obtaining informed consent. Allocating the samples to the groups will be done with a table of random numbers. After the initial diagnosis by the vascular surgeon, the patients are referred to the student administrator for grouping and randomization, and the student does not know the type of treatment of the patients.

Settings and conduct

All patients have medical records and are visited every two months. Patients who do not complete the treatment or do not return will be excluded from the study. According to the number of prescription drugs and bimonthly visits, the compliance rate of patients is evaluated. Full compliance with the prescription is essential. The change in the patient's symptoms and vcss score following the intervention is the outcome of the study. The initial, serial and final examinations of the patient are performed by the vascular surgeon and the patients' information is recorded.

Participants/Inclusion and exclusion criteria

-Chronic venous insufficiency disease with class C2 and more - Ability to communicate - Not having a history of psychiatric illness Consent to take medicine

Intervention groups

The study will be completed by a clinical trial method with a sample size of 100 people in two groups of 50 people by patients who will refer to the vascular surgery center due to chronic venous insufficiency. The first group takes pentoxifylline 400 mg every 8 hours and the second group takes Daflon 500 mg every 12 hours for 6 months.

Main outcome variables

increase in venous tone; suppression of inflammatory reactions; significant reduction in leg size; improving patient performance; Reduce limb pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221213056808N1**
Registration date: **2023-04-17, 1402/01/28**
Registration timing: **registered_while_recruiting**

Last update: **2023-04-17, 1402/01/28**
Update count: **0**

Registration date

2023-04-17, 1402/01/28

Registrant information

Name

Iman Heidari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 17 3252 7741

Email address

imanheidari72@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-20, 1401/12/01

Expected recruitment end date

2024-03-19, 1402/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
investigation and Comparison of the effect of Daflon and pentoxifylline in the treatment of patients with chronic venous insufficiency

Public title
investigation and Comparison of the effect of Daflon and pentoxifylline in the treatment of patients with chronic venous insufficiency

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Chronic venous insufficiency disease with class C2 and more according to CEAP criteria Consent to take medicine Ability to communicate

Exclusion criteria:
Patients who are candidates for surgery Patients who do not take medicine

Age
No age limit

Gender
Both

Phase
1-2

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
Allocation of samples to groups will be done with a table of random numbers. In this way, the substitutions of ABC-ACB-BAC-BCA-CAB-CBA and assigning code 1 to 6 will be done. In the table of random numbers, a single-digit number will be randomly selected and moved down, and with each number obtained, the corresponding place of those samples will be assigned to groups. If the numbers zero, 7, 8 and 9 are obtained, they will not be considered.

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients will not know their allocation to study groups. Allocation of the samples to the studied groups will be done by the respected vascular surgeon and based on the table of random numbers, and the student will not know about it either.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Golestan University of Medical Sciences

Street address
5 Azar Street, 5 Azar Hospital, Surgery Department

City
Gorgan

Province
Golestan

Postal code
4917761551

Approval date
2023-01-01, 1401/10/11

Ethics committee reference number
IR.GOUMS.REC.1401.480

Health conditions studied

1

Description of health condition studied
Patients with chronic venous insufficiency

ICD-10 code
I87.2

ICD-10 code description
Venous insufficiency (chronic) (peripheral)

Primary outcomes

1

Description
CEAP(classification stands for Clinical (C), Etiological (E), Anatomical (A), and Pathophysiological (P)) Score

Timepoint
At the beginning of the study and 6 months after taking the drug

Method of measurement
C0: no obvious features of the disease: C1: spider veins C2: obvious varicose veins: C3: edema: C4: eczema and skin discoloration: C5: healing wounds C6: active wounds with exudation

2

Description
Venous Clinical Severity Score(vcss score)

Timepoint
At the beginning of the study and 6 months after taking the drug

Method of measurement
Pigmentation: 0-2 Vascularity: 0-5 Pliability: 0-5 Height: 0-3

Secondary outcomes

empty

Intervention groups

1

Description
The first intervention group: patients who entered the study according to the inclusion criteria and were treated with pentoxifylline tablets (from Farabi company) at a dose of 400 mg three times a day for 6 months.
Category
Treatment - Drugs

2

Description
The second intervention group: patients who entered the study according to the inclusion criteria and were treated with Daflon tablets 500 mg twice a day for 6 months.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
5 Azar hospital
Full name of responsible person
Iman Heidari
Street address
5 Azar St
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4917761551
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Gorgan University of Medical Sciences
Full name of responsible person
Narges beigom Mirbehbahani
Street address
Research and Technology Vice-Chancellor,2nd Floor,Central Library Building,Higher Philosophical Education Complex,Shasat Kala Road,gorgan
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Golestan
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Phone
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Email
n.mirbehbahani@gmail.com
Web page address
https://goums.ac.ir/index.php?slc_lang=fa&sid=12
Grant name
.
Grant code / Reference number
.
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Gorgan 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
Gorgan University of Medical Sciences
Full name of responsible person
Iman Heidari
Position
General surgery assistant
Latest degree
Medical doctor
Other areas of specialty/work
General Surgery
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Person responsible for scientific inquiries

Contact
Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person
Pezhman Kharazm

Position
Assistant Professor

Latest degree
Subspecialist

Other areas of specialty/work
Vascular Surgery

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Surgery Department Office ;Shahid Nabawi Building; fifth floor; 5 Azar Hospital

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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Position
General Surgery Assistant

Latest degree
Medical doctor

Other areas of specialty/work
General Surgery

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Farhang building ; Edalat 61 ; Naharkhoran Boulevard

City
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Golestan

Postal code
4917845653

Phone
+98 17 3252 7741

Email
Imanheidari72@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is 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
After conducting a study on patients who have taken two drugs, Daflon and Pentoxifylline, for a certain period of time, all the classified data can be shared after de-identifying the patients.

When the data will become available and for how long
The access period starts 1 month after the results are published

To whom data/document is available
The data will be available to all researchers working in academic and scientific institutions as well as people working in the industry.

Under which criteria data/document could be used
There is no specific limitation.

From where data/document is obtainable
Dr Iman Heidari mobile:09113222421 email: imanheidari72@gmail.com

What processes are involved for a request to access data/document
The reason for the request regarding the data and the subject of study should be emailed to the desired address, as soon as it is reviewed, it will be provided to the requester in the shortest possible time.

Comments