Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jul 2026

The effect of a six-month combined care program with garlic supplementation on coagulation factors (INR, PTT, PT), Fibrinogen and platelets in middle-aged men with deep vein thrombosis (DVT)

Protocol summary

Study aim

Evaluation of the effect 6 months of combined training with garlic supplementation on coagulation factors (INR, PPT, PT), fibrinogen and platelets in men with DVT

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 40 patients. Excel software rand function was used for randomization.

Settings and conduct

This research was conducted experimentally with a clinical trial design. Subjects in this study included 40 middle-aged men aged 40 to 60 years with deep vein thrombosis (DVT) in Kermanshah. Subjects were available as a sample and met the inclusion criteria. In line with the research objectives, the subjects were randomly divided into four groups; 1. Combined exercise (resistance-aerobic) + garlic supplement (10 people), 2. Combined exercise (10 people), 3. Garlic supplement (10 people) and 4. Control group (10 people) by randomization method using Excel function rand functions were divided. In line with the objectives of the two-way blind study: both the researcher and the participants did not know about the supplement used in the supplement and placebo groups. .

Participants/Inclusion and exclusion criteria

Man Middle age 40 to 60 years With deep vein thrombosis No other diseases No motor disability

Intervention groups

1. Combined exercise group (resistance - aerobic): Combined exercise was performed for 24 weeks with 3 sessions per week. 2. Garlic consumption group: Garlic supplement consumption in the present study was 1200 mg daily as one capsule per day and in the control group placebo (1200 mg starch) was used. Garlic extract capsules were obtained from the Ministry of Agriculture and the Ministry of Agriculture. 3. Combined exercise group and garlic consumption: included both combined exercise and the use of garlic supplements. 4. Control group: It was the use of placebo.

Main outcome variables

Combined exercise; Garlic

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210718051924N1**
Registration date: **2021-08-22, 1400/05/31**
Registration timing: **retrospective**

Last update: **2021-08-22, 1400/05/31**
Update count: **0**

Registration date

2021-08-22, 1400/05/31

Registrant information

Name

Hamed Saed

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

hamedsaed1@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-22, 1399/05/01

Expected recruitment end date

2021-01-20, 1399/11/01

Actual recruitment start date

2020-07-22, 1399/05/01

Actual recruitment end date

2021-01-20, 1399/11/01

Trial completion date

2021-01-29, 1399/11/10

Scientific title

The effect of a six-month combined care program with garlic supplementation on coagulation factors (INR, PTT, PT), Fibrinogen and platelets in middle-aged men with deep vein thrombosis (DVT)

Public title

The effect of a course of exercise with garlic supplementation on some coagulation factors in middle-aged men with deep vein thrombosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Middle-aged men 40 to 60 years old with deep vein thrombosis (DVT) in Kermanshah

Exclusion criteria:

Age

From **40 years** old to **60 years** old

Gender

Male

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **40**

Actual sample size reached: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

First, using the library, field and laboratory methods, measures were taken to collect information about the intervention. After identifying individuals with deep vein thrombosis (DVT) and selecting the research sample, the participants' consent to complete the study was completed. After obtaining the consent to participate in the research, the samples were randomly divided into 4 groups of 10 people: Group 1: Resistance (who performed the designed combined exercises) 2: Garlic consumption group (who consumed garlic according to the plan) 3: Combined exercise with garlic (who did the designed combined exercises and also consumed garlic) 4: Control (did not participate in any of the sports activities) Group 1, 8 weeks, did 3 sessions of combined exercise every week. All exercise programs, starting with the principle of overload, increasingly started from the first week and continued until the end of the eighth week. The experiments were performed in two stages, one day before the first training session (pre-test) and 48 hours after the last training session (post-test) in the eighth week of training, after 10 to 12 hours of fasting. It should be noted that all subjects, in addition to the intervention, continued to take warfarin tablets to the extent prescribed by the doctor for each person during the treatment period, and the amount and timing was determined by each person's doctor. The combined exercise program was performed for 24 weeks with a frequency of 3 days a week, combining aerobic and resistance exercises. Weight movements in 2 sets and 10 to 12 repetitions will include chest press, wire pull side pull, boat pull, leg press and bending and opening the thigh. Exercises started with 40% of a maximum repetition and lasted 22 minutes. In the aerobic section, the subjects trained for 22 minutes with an intensity of 40% of maximum heart rate (HRmax). At 4 weeks the intensity of the exercises was re-evaluated. At the beginning of the sessions they had 3 to 5 minutes of warm-up time and at the end of 3 to 5 minutes they had time to cool down

Blinding (investigator's opinion)

Double blinded

Blinding description

Both the researcher and the participants

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kermanshah University of Medical Sciences

Street address

Kermanshah University of Medical Sciences

City

Kermanshah

Province

Kermanshah

Postal code

6714869914

Approval date

2020-12-22, 1399/10/02

Ethics committee reference number

IR.KUMS.REC.1399.1035

Health conditions studied

1

Description of health condition studied

Deep vein thrombosis (DVT)

ICD-10 code

I82.4

ICD-10 code description

Acute embolism and thrombosis of deep veins of lower extremity

Primary outcomes

1

Description
Prothrombin Time (PT)Partial Thromboplastin Time (PTT)International Normalization Ratio (INR), Fibrinogen, platelets
Timepoint
24 hours before the start of the study and 48 hours after the last training session after 24 weeks
Method of measurement
It was measured by class coagulation method with laboratory kits (ACL) and fully automatic device (ACL 8000 made in Italy).

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Combined exercise (resistance training + aerobic exercise): The combined exercise program was performed for 24 weeks with a frequency of 3 days a week, combining aerobic and resistance exercises. Weight movements in 2 sets and 10 to 12 repetitions will include chest press, wire pull side pull, boat pull, leg press and bending and opening the thigh. Exercises started with 40% of a maximum repetition and lasted 22 minutes. In the aerobic section, the subjects trained for 22 minutes with an intensity of 40% of maximum heart rate (HRmax). At 4 weeks the intensity of the exercises was re-evaluated. At the beginning of the sessions they had 3 to 5 minutes of warm-up time and at the end of 3 to 5 minutes they had time to cool down.
Category
Treatment - Drugs

2

Description
Intervention group 2: Use of garlic supplement: Garlic supplement consumption in the present study was 1200 mg daily as one capsule per day and in the control group placebo (1200 mg of starch) was used. The garlic extract was prepared from the American Nature Company with a health license from the General Directorate of Food Supervision of the Ministry of Health.
Category
Treatment - Drugs

3

Description
Intervention group 3: Combined exercise (resistance training + aerobic exercise): The combined exercise program was performed for 24 weeks with a frequency of 3 days a week, combining aerobic and resistance exercises. Weight movements in 2 sets and 10 to 12 repetitions will include chest press, wire pull side pull, boat pull, leg press and bending and opening the thigh. Exercises started with 40% of a maximum repetition and lasted 22 minutes. In the aerobic section, the subjects trained for 22 minutes with an intensity of 40% of maximum heart rate (HRmax). At 4 weeks the intensity of the exercises was re-evaluated. At the beginning of the sessions they had 3 to 5 minutes of warm-up time and at the end of 3 to 5 minutes they had time to cool down. Garlic supplement consumption in the present study was 1200 mg daily as one capsule per day and in the control group placebo (1200 mg of starch) was used. The garlic extract was prepared from the American Nature Company with a health license from the General Directorate of Food Supervision of the Ministry of Health.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital in Kermanshah
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
Islamic Azad University
Proportion provided by this source
10
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
Islamic Azad University
Full name of responsible person
Hamed Saed
Position
PhD student
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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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
After the study, I will make the result transparently available for publication in the Islamic Azad University, Kermanshah Branch.
When the data will become available and for how long

After the end of the study in early August 2016

To whom data/document is available

Islamic Azad University, Kermanshah Branch

Under which criteria data/document could be used

To inform patients of deep vein thrombosis treated with warfarin about the risk of blood clots or leg bleeding regarding recovery after using one of these study methods

From where data/document is obtainable

Hamed Saed

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

The request must be in writing and from the Islamic Azad University of Kermanshah

Comments