

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Association the combined and separate effects of the DASH diet and vitamin D supplementation on inflammatory markers and improvement of heart condition in patients with heart failure

Protocol summary

Study aim

Our goal of this study is to know what effect the intervention has on hsCRP, ESR, lipid profile, blood sugar, appetite, fatigue, blood pressure, anthropometric indices, pulse rate and exercise test results in heart failure patients.

Design

The clinical trial has a control group and is factorial. This study is open label and has 120 patients. STATA version 16 software is used for randomization.

Settings and conduct

In this study, 120 people with heart failure will be divided into two intervention and control groups. The place where the study is conducted is in the Cardiac Rehabilitation Center and Clinic of Chamran Hospital, Isfahan. This study is open. The assessor, the laboratory and the epidemiologist were blinded to the method of intervention.

Participants/Inclusion and exclusion criteria

Entry requirements: willingness to cooperate with the project Age 40 to 65 years Patients with FH heart failure The ability to consume food properly Vitamin D levels less than 30 ng/ml. Conditions of non-entry: pregnancy, breastfeeding, hospitalization malignancy Use of dietary supplements Follow a special diet Chronic kidney disease Consumption of vitamin D supplements Patients who do not have normal levels of creatine and urea. In other words, people whose EF is less than 40.

Intervention groups

This study has four groups and 30 people have been allocated for each group. The first group receive vitamin D, the second group will receive DASH diet, and the third group will receive both interventions (vitamin D and DASH diet) at the same time. The fourth group (control) receives placebo .

Main outcome variables

Blood pressure, pulse rate, appetite, lipid profile, blood

sugar, fatigue, exercise test, hsCRP,ESR,

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171205037760N2**

Registration date: **2023-08-08, 1402/05/17**

Registration timing: **prospective**

Last update: **2023-08-08, 1402/05/17**

Update count: **0**

Registration date

2023-08-08, 1402/05/17

Registrant information

Name

ABBAS ABBASI

Name of organization / entity

Country

Iran (Islamic Republic of)

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arvinabbasi55@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-01, 1402/06/10

Expected recruitment end date

2023-12-06, 1402/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Association the combined and separate effects of the DASH diet and vitamin D supplementation on inflammatory markers and improvement of heart condition in patients with heart failure

Public title

Association the combined and separate effects of the DASH diet and vitamin D supplementation on inflammatory markers and improvement of heart condition in patients with heart failure

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Willingness to cooperate with the plan 40 to 65 years old Patients with stage 1 of heart failure. In other words, patients with an %EF between 40 and 50 are included in the study. The ability to consume food properly (in other words, those patients will be selected who have the ability to consume vegetables and fruits, for example, have teeth suitable for chewing, are not hospitalized, have the ability and ability to prepare food, and or someone prepares it for them) Vitamin D levels less than 30 ng/ml

Exclusion criteria:

Pregnancy, breastfeeding, hospitalization and Malignancy Use of nutritional supplements in the last 3 months Following a special diet• Chronic kidney disease Consumption of vitamin D supplements in the last three months. Patients who do not have normal levels of creatine and urea People with moderate and severe %EF. In other words, people whose %EF is less than 40

Age

From **40 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **120**

More than 1 sample in each individual

Number of samples in each individual: **1**

In this study, 120 people will be divided into intervention and control groups based on the specified sample size formula. 30 people in the first group will receive only vitamin D, and another 30 people in the second group will only receive the DASH diet, and another 30 people in the third group will receive both interventions (vitamin D and the DASH diet) at the same time, and the fourth group or control receives placebo control. The control group is also 30 people.

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, to allocate people in the intervention and control groups, we use the block method and we use the

eight block method, and according to this blocking, the chance of assigning people to each of the four groups will be the same. . Our sample size is 120 people, 90 people will be in the intervention group and 30 people will be in the control group. Random allocation method is block classification using Stata software version 16. Blocking will be done by an epidemiologist.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Used

Assignment

Factorial

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Eefahan University of Medical Sciences

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Hazar Jarib Street, Isfahan University of Medical Sciences

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Approval date

2023-07-31, 1402/05/09

Ethics committee reference number

IR.MUI.RESEARCH.REC.1402.168

Health conditions studied**1****Description of health condition studied**

HEART FAILURE

ICD-10 code

I50.33

ICD-10 code description

Acute on chronic diastolic (congestive) heart failure

Primary outcomes**1****Description**

hsCRP: One of the heart risk markers used to help determine a person's risk. It will be measured using immunoturbidometry.

Timepoint

At the beginning of the study and two months after the intervention

Method of measurement

laboratory measurements, It is measured by immunoturbidometry.

2

Description

ESR: erythrocyte sedimentation rate (ESR); It is an indirect measure of the degree of inflammation in the body. This test measures the sedimentation rate of red blood cells in a blood sample placed in a long, narrow, vertical tube.

Timepoint

At the beginning of the study and two months after the intervention

Method of measurement

A long, narrow and vertical pipe is used for measuring. The result of the ESR test is recorded in millimeters and the duration of red blood cell sedimentation is considered. The normal level of this test is 0-29 for women and 0-22 for men.

3

Description

Assessment of malnutrition: Check possible malnutrition in patients during treatment.

Timepoint

At the beginning of the study and two months after the intervention

Method of measurement

It is measured through Mini nutritional assessment questionnaire .

4

Description

What is blood pressure: Normal blood pressure is a vital function of the body. Blood pressure is the force that propels blood through our circulatory system, bringing oxygen or nutrients to tissues and organs through arteries.

Timepoint

At the beginning of the study and two months after the intervention

Method of measurement

blood pressure monitor

5

Description

Blood fat test or lipid profile is a combination of tests that are considered to check the risks of coronary heart disease and include markers (LDL, HDL, TRIGLYCERIDE, TOTAL CHOLESTEROL) or as a preventive measure to check risks related to factors such as: Eating habits, diet, stress, exercise and lifestyle are done.

Timepoint

At the beginning of the study and two months after the intervention

Method of measurement

through laboratory kits for measuring LDL, HDL, THREE TRIGLYCERIDE, TOTAL CHOLESTEROL

6

Description

glucose reaches the body through food. After digesting carbohydrates, the body turns them into sugar that circulates in the blood. Blood sugar is necessary for the body to receive energy and is the so-called source of body energy.

Timepoint

At the beginning of the study and two months after the intervention

Method of measurement

Blood glucose kit

7

Description

Appetite is desire for food.

Timepoint

At the beginning of the study and two months after the intervention

Method of measurement

Questionnaire

8

Description

Cardiac exercise test is one of the necessary tests to check the heart's performance in active mode. The cardiologist requests this test to check the possibility of heart diseases in the patient. This test is one of the body checkup tests for people with heart problems. In this test, the patient usually walks on a regular treadmill according to the Bruce protocol or a similar exercise program, until the heart rate reaches the expected level or certain symptoms appear in the person. The process of performing this test is that heart function and blood pressure are checked in the exercise test, before, during and after the exercise test. These tests help the doctor to diagnose the problem.

Timepoint

At the beginning of the study and two months after the intervention

Method of measurement

First, the pulse, blood pressure and heart rate are measured and then they are measured and recorded repeatedly during the test. After the heart examination, it will be placed on the treadmill for the exercise test. This device is a movable and rolling rubber plate (similar to a conveyor) on which the patient stands and must walk on it to maintain balance. Every 3 minutes, the slope of the strip will increase by 2% and its speed will increase by 1.2 km per hour.

Secondary outcomes

empty

Intervention groups

1

Description

In intervention 1, 30 patients received only vitamin D. The intake of vitamin D is once a week and its duration is for two months. The supplement is given to the patients by the researcher. The supplement will be provided by Dana Pharmaceutical Company, which is available in the food supplement market under the name of vitamin D3 under the brand name D Vigil and is approved by relevant organizations.

Category

Rehabilitation

2

Description

Intervention group 2: In this group, which is about 30 people, they receive DASH diet advice. This diet is based on the consumption of vegetables, fruits, low-fat dairy products and nuts. In this diet, the consumption of red meat, sweets and solid oil is reduced.

Category

Rehabilitation

3

Description

Intervention group 3: In this group, which has 30 people, they receive vitamin D and DASH diet at the same time. They receive vitamin D 50,000 every week for a period of two months. The supplement will be provided by Dana Pharmaceuticals, which is available in the nutritional supplement market under the name vitamin D3 under the brand name D Vigil, and the group will also receive DASH diet recommendations based on calorie needs.

Category

Rehabilitation

4

Description

Control group, which has 30 people, they receive placebo vitamin D. Placebo contains gel and is given to patients once a week for two months. This group of patients does not receive the DASH diet.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Chamran hospital

Full name of responsible person

Masomeh Sadeghi

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Masomeh Sadeghi

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

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Morteza Safavi

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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

Laboratory results and clinical evaluations can be shared

When the data will become available and for how long

Access 6 months after results are printed

To whom data/document is available

Accessibility for academics

Under which criteria data/document could be used

They are only allowed to study

From where data/document is obtainable

researcher

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

The application must be submitted through a scientific center to Isfahan University of Medical Sciences, Faculty of Nutrition

Comments