

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Investigating biochemical parameters and functional capacity in obese patients with coronary artery occlusive disease trained with a short-term diet

Protocol summary

Study aim

Determining the effect of short-term dietary intervention on biochemical parameters and functional capacity in obese patients with obstructive coronary artery disease.

Design

A clinical trial with a control group, double-blind, simple randomization based on the block method on 100 patients.

Settings and conduct

All obese patients with coronary artery occlusive disease, who were divided into two control and intervention groups based on simple randomization using the block method, and the patients of each group were invited to the ground floor of Razi Hospital on an empty stomach according to the previous invitation, and the group Intervention After taking the initial tests and performing the functional capacity test (6-minute walk), they are referred to the nutritionist clinic to receive a diet, and the control group is not subjected to any diet.

Participants/Inclusion and exclusion criteria

Eligibility criteria: Coronary patient confirmed to have at least 50% narrowing of the artery; BMI greater than 30; Consent to participate in the study. Exclusion criteria: People with hyperthyroidism; Any type of musculoskeletal disease that prevents patients from walking; Any known cancers in patients; Known kidney disease in patients (such as types of glomerulonephritis or patients undergoing routine dialysis); Known liver disease in patients (such as types of viral hepatitis and autoimmune hepatitis);

Intervention groups

Intervention group: diet recipient Control group: no diet

Main outcome variables

Distance traveled in the 6 Minutes walking test; Level of fasting blood sugar; Level of lipid profile (LDL, Chol, TG, HDL); SGOT serum level; SGPT serum level; BMI and waist circumference; HbA1C; Systolic and diastolic blood

pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230731058983N1**

Registration date: **2023-11-14, 1402/08/23**

Registration timing: **prospective**

Last update: **2023-11-14, 1402/08/23**

Update count: **0**

Registration date

2023-11-14, 1402/08/23

Registrant information

Name

Azadeh Akbari

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-17, 1402/08/26

Expected recruitment end date

2024-05-14, 1403/02/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating biochemical parameters and functional capacity in obese patients with coronary artery occlusive disease trained with a short-term diet

Public title

Investigating biochemical parameters and functional capacity in obese patients with coronary artery occlusive disease trained with a short-term diet

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

coronary artery disease with at least 50% stenosis BMI more than 30 patient satisfaction Age above 18 years

Exclusion criteria:

coronary artery disease with less than 50% stenosis BMI less than 30 patients with hyperthyroidism Any type of musculoskeletal and rheumatologic disease that prevents patients from walking Age under 18 years Any known cancers in patients Known chronic kidney disease in patients (such as types of glomerulonephritis or patients undergoing routine dialysis) Known liver disease in patients (such as types of viral hepatitis and autoimmune hepatitis) Immunocompromised patients People with disabilities Bedridden people

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

The method of randomization of patients in this study will be block randomization and the blocks will be considered quadruple in this study. The tool for randomization and creating a random sequence will be Excel software. The random between function will be used to create a random sequence. Random blocks will be placed in numbered sealed envelopes. After randomly selecting each envelope, the desired block will be removed from the statistical sample and the sampling will continue until the work is completed.

Blinding (investigator's opinion)

Double blinded

Blinding description

The blinding used in this study will be double-blind. In other words, in this study, the patients and the person evaluating the study will not know the assignment of the group to the studied arms, and it will be specified as A

and B in the data collection form. In this study, we do not have a placebo, but the studied groups are not related to each other, because in the call, conditions are provided in such a way that it is not possible for people to meet each other. In terms of physical activity, the two groups will have routine conditions so that it is possible to examine the effect of diet closer to reality. In this study, the outcomes studied will include biochemical factors and the 6-minute walk test, which is observed by a third person (a person who not the principal investigator of the study) will be done to avoid detection bias.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Birjand University of Medical Science

Street address

Faculty of medicine, University of Medical Science, Ghaffari Blvd

City

Birjand

Province

South Khorasan

Postal code

9117844471

Approval date

2023-07-24, 1402/05/02

Ethics committee reference number

IR.BUMS.REC.1402.200

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

coronary artery disease

ICD-10 code

I25.1

ICD-10 code description

Atherosclerotic heart disease of native coronary artery

2**Description of health condition studied**

obesity

ICD-10 code

E66.0

ICD-10 code description

Obesity due to excess calories

3

Description of health condition studied

blood pressure

ICD-10 code

Z01.3

ICD-10 code description

Examination of blood pressure

4

Description of health condition studied

diabet

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes

1

Description

distance covered in the 6 Minutes Walking test

Timepoint

at 0 and 3 months after the intervention in the two investigated groups.

Method of measurement

Checking the distance traveled during 6 minutes

2

Description

level of fasting blood sugar

Timepoint

Time zero and 3 months after the intervention in the two studied groups

Method of measurement

Hospital laboratory kit

3

Description

serum level of lipid profile (LDL, Chol, TG, HDL)

Timepoint

Time zero and 3 months after the intervention in the two studied groups

Method of measurement

Hospital laboratory kit

4

Description

serum levels of SGOT and SGPT

Timepoint

Time zero and 3 months after the intervention in the two studied groups

Method of measurement

Hospital laboratory kit

5

Description

BMI and waist circumference

Timepoint

Time zero and 3 months after the intervention in the two studied groups

Method of measurement

scale and meter

6

Description

HbA1C

Timepoint

Time zero and 3 months after the intervention in the two studied groups

Method of measurement

Hospital laboratory kit

7

Description

average systolic and diastolic blood pressure

Timepoint

Time zero and 3 months after the intervention in the two studied groups

Method of measurement

blood pressure device

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: All patients in the intervention group are provided with a three-month short-term balanced diet by a nutritionist. This visit will last for at least half an hour and a short-term diet will be provided to each patient based on a balanced diet, and the necessity of following the diet and the importance of weight loss will be explained to the patient, and it will be emphasized to them that During this period, do not make any other changes in your lifestyle, such as starting a club sports program. Patients are followed up monthly to ensure compliance with the diet.

Category

Lifestyle

2

Description

Control group: all patients of the control group refer to the study site according to the previous call and the aforementioned tests and the 6-minute walk test are taken from them and without receiving a special diet and advice not to change their daily diet, again after three months. They will be called and the mentioned tests and the 6-minute walk test will be taken from them again.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Birjand University of Medical Science, Razi Hospital

Full name of responsible person

Azadeh Akbari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Dr.Tooba Kazemi

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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

Birjand 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

Birjand University of Medical Sciences

Full name of responsible person

Azadeh Akbari

Position

Resident of Cardiology

Latest degree

Medical doctor

Other areas of specialty/work

Cardiology

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Position

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Person responsible for updating data

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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

All data is potentially shareable after de-identifying individuals.

When the data will become available and for how long

The access period starts 6 months after the results are published.

To whom data/document is available

Researchers working in scientific-university institutions (with reference to the source).

Under which criteria data/document could be used

The use of the documentation of the article for other research works is unimpeded by mentioning the source.

From where data/document is obtainable

Dr. Azadeh Akbari, Cardiac Resident, Birjand University of Medical Sciences, 09154448212

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

Non-identifiable data of individuals as well as the study protocol will be available to other researchers (with reference to the source) 6 months after the publication of the article.

Comments

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