Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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
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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 and3 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
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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
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
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Person responsible for scientific inquiries

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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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