Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jul 2026

Determining the effect of following a two-meal diet eliminating lunch on risk and predictive factors of cardiovascular diseases: A clinical trial

Protocol summary

Study aim
Determining the effect of following a two-meal diet by eliminating lunch on risk factors and predictors of cardiovascular disease
Design
A randomized controlled trial with parallel group, double blind, randomized, phase 3, with sample size: 120, randomization will be done by Random Allocation
Settings and conduct
This randomized controlled trial will be conducted in Imam Hossein hospital, Semnan, Iran
Participants/Inclusion and exclusion criteria
People who are able to have two-meal diet
Intervention groups
Intervention group: people who have had a three-meal diet and changed it to a two-meal diet. Control group: having three-meal diet
Main outcome variables
To measure the effect of the intervention, oxidative, apoptotic and inflammatory factors will be measured. Also, to assess this intervention, the predictive factors of cardiovascular diseases will be examined.

General information

Reason for update
Acronym
TDS
IRCT registration information
IRCT registration number: **IRCT20200411047024N2**
Registration date: **2021-11-01, 1400/08/10**
Registration timing: **prospective**

Last update: **2021-11-01, 1400/08/10**
Update count: **0**
Registration date
2021-11-01, 1400/08/10

Registrant information
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Hossein Sheibani
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-12-22, 1400/10/01
Expected recruitment end date
2022-10-23, 1401/08/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Determining the effect of following a two-meal diet eliminating lunch on risk and predictive factors of cardiovascular diseases: A clinical trial

Public title
Effect of two-meal diet on cardiovascular system
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
person's desire to participate in the trial Having the physical ability to complete the trial No prohibition to comply with the diet Having no special diet beforehand Lack of acute phase of inflammatory diseases and the gastrointestinal tract disorders Having the body mass

index above 24.9 No history of ulcers and inflammation of the upper gastrointestinal tract, as well as a history of gastrointestinal bleeding and inflammatory diseases of the gastrointestinal tract, including Crohn's disease and ulcerative colitis.

Exclusion criteria:

Lack of desire to participate in the trial Lack of physical ability to complete the trial Have been banned on trial diet Having special diet Acute phase of inflammatory diseases and the gastrointestinal tract disorders History of ulcers and inflammation of the upper gastrointestinal tract, as well as a history of gastrointestinal bleeding and inflammatory diseases of the gastrointestinal tract, including Crohn's disease and ulcerative colitis. Advanced diabetes mellitus or insulin-mediated diabetes mellitus due to the potential for damage due to reactive hypoglycemia History of previous recurrent hypoglycemia Having severe debilitating disorders at the same time Consumption high-dose corticosteroids, chemotherapy drugs, and cytotoxic drugs Having untreated glandular diseases, especially thyroid and adrenal disorders Body mass index less than 25

Age

From **35 years** old

Gender

Both

Phase

3

Groups that have been masked

- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

This will be a simple random sampling study. Each person is considered as a randomization unit. Random Allocation online software is used for this purpose. In this study, a code is assigned to patients, then these codes, which are in the form of consecutive numbers, are entered into randomization software and this software randomly places people in two groups. Then people enter the assigned group based on the code.

Blinding (investigator's opinion)

Double blinded

Blinding description

This research will be done in form of double blind. Due to the fact that it is not possible to blind the subjects, in this study only the physician and nurse who collects and imports information into the software and the statistical consultant will be unaware of the presence of patients in the intervention and control groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of The Qom University of Medical Sciences

Street address

Shahid Lavasani (Saheli) St., Qom, I.R. Iran

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Approval date

2021-08-22, 1400/05/31

Ethics committee reference number

IR.MUQ.REC.1400.95

Health conditions studied

1

Description of health condition studied

Cardiovascular disorders

ICD-10 code

I51.6

ICD-10 code description

Cardiovascular disease, unspecified

Primary outcomes

1

Description

Weight

Timepoint

Beginning and end of the study

Method of measurement

Scales

2

Description

Blood pressure

Timepoint

Beginning and end of the study

Method of measurement

Sphygmomanometer

3

Description

Functional status of systole and diastole of left ventricular

Timepoint

Beginning and end of the study

Method of measurement

Transthoracic echocardiography

4

Description

Body fat percentage

Timepoint

Beginning and end of the study

Method of measurement

Bioelectrical impedance device

5

Description

Carotid intimal thickness

Timepoint

Beginning and end of the study

Method of measurement

Carotid sonography

6

Description

CRP serum level

Timepoint

Beginning and end of the study

Method of measurement

CRP kit quantitatively made by Pishtazteb company

7

Description

Lipid profile

Timepoint

Beginning and end of the study

Method of measurement

Lipid assay kit

8

Description

The level of malonyl dialdehyde

Timepoint

Beginning and end of the study

Method of measurement

Standard kit of malonyl dialdehyde

9

Description

The level of BAX

Timepoint

Beginning and end of the study

Method of measurement

Standard kit of BAX

10

Description

The level of Bcl2

Timepoint

Beginning and end of the study

Method of measurement

Standard kit of Bcl2

11

Description

Fasting Blood Sugar Test

Timepoint

Beginning and end of the study

Method of measurement

glucometer

12

Description

HbA1c

Timepoint

Beginning and end of the study

Method of measurement

affinity chromatography methods

13

Description

uric acid test

Timepoint

Beginning and end of the study

Method of measurement

Uric acid laboratory test kit

14

Description

Hip circumference size

Timepoint

Beginning and end of the study

Method of measurement

sewing meter

15

Description

Waist size

Timepoint

Beginning and end of the study

Method of measurement

sewing meter

16

Description

Serum insulin levels

Timepoint

Beginning and end of the study

Method of measurement

Laboratory Insulin Assay Kit

17

Description

insulin resistance

Timepoint

Beginning and end of the study

Method of measurement

Oral glucose tolerance test

18

Description
serum glutathione
Timepoint
Beginning and end of the study
Method of measurement
Glutathione Laboratory Assay Kit

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: This group has a two-meal diet, which means that only two meals will be served in 24 hours. This diet will last for 16 weeks (4 months). The first meal will be in the early morning and the second meal in the evening
Category
Lifestyle

2

Description
Control group: The normal diet, which is three meals a day
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hossein Hospital of Shahroud
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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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
Research Deputy of The Qom 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
Shahroud University of Medical Sciences
Full name of responsible person
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Position
Assistant Professor of Cardiology Department of Clinical Sciences, School of Medicine
Latest degree
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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
Some of the information about the main outcome will be available to be published
When the data will become available and for how long
Access period starts 3 months after publishing of results
To whom data/document is available
It will be available to researchers working in academic and scientific institutions
Under which criteria data/document could be used
There should be no conflict of interest. Responsibility and maintaining the ethics of the researcher
From where data/document is obtainable
Contact Dr. Hossein Sheibani via email: sheybani@shmu.ac.ir
What processes are involved for a request to access data/document
Citing the RCT code and the study done and the reason for the need for the results with the mentioned conditions can send the request
Comments