

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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

Name

Hossein Sheibani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3239 2820

Email address

sheybani@shmu.ac.ir

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

City

Qom

Province

Ghoum

Postal code

3716993456

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

Hossein Sheibani

Street address

Imam Hossein Hospital of Shahroud, Baghzendan street, Shahroud, Semnan, Iran

City

Shahroud

Province

Semnan

Postal code

3619611151

Phone

+98 23 3234 2000

Email

sheybani@shmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Deputy of The Qom University of Medical Sciences

Full name of responsible person

Ehsan Sharifipour

Street address

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

City

Qom

Province

Ghoum

Postal code

3716993456

Phone

+98 25 3285 4011

Email

research@muq.ac.ir

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

Hossein Sheibani

Position

Assistant Professor of Cardiology Department of Clinical Sciences, School of Medicine

Latest degree

Subspecialist

Other areas of specialty/work

Cardiology

Street address

Shahroud University of Medical Sciences, Tehran Blvd, Hafte Tir Square

City

Shahroud

Province

Semnan

Postal code

3614773955

Phone
+98 23 3239 1609
Email
sheybani@shmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahroud University of Medical Sciences
Full name of responsible person
Hossein Sheibani
Position
Assistant Professor of Cardiology Department of Clinical Sciences, School of Medicine
Latest degree
Subspecialist
Other areas of specialty/work
Cardiology
Street address
Shahroud University of Medical Sciences, Tehran Blvd,
Hafte Tir Square
City
Shahroud
Province
Semnan
Postal code
3614773955
Phone
+98 23 3239 1609
Email
sheybani@shmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Shahroud University of Medical Sciences
Full name of responsible person
Hossein Sheibani
Position
Assistant Professor of Cardiology Department of Clinical Sciences, School of Medicine
Latest degree
Subspecialist
Other areas of specialty/work
Cardiology
Street address

Shahroud University of Medical Sciences, Tehran Blvd,
Hafte Tir Square

City
Shahroud
Province
Semnan
Postal code
3614773955
Phone
+98 23 3239 1609
Email
sheybani@shmu.ac.ir

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