Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Jun 2026

The effect of low calorie diet with and without sibutramine on metabolic syndrome risk factors and sonographic findings in non alcoholic fatty liver

Protocol summary

Summary
This randomized double blind controlled trial was performed to determine the effect of low-calorie diet with and without sibutramine on risk factors of metabolic syndrome and ultrasound findings in 40 patients with non-alcoholic fatty liver (confirmed by ultrasound). After 12-14 hours fasting, blood sample was taken and concentration of triglyceride, glucose, AST, ALT, HbA1c and serum ferritin, total cholesterol, HDL-c, and LDL-c are checked and weight and height of the patients were measured by standard methods. Then the patients were assigned receive 15-mg capsules of sibutramine daily half an hour before lunch as well as vitamin E supplements (400 IU) once a day and weight loss diet for 3 months or only vitamin E supplement (400 IU) once a day and weight loss diet for 3 months. At the end of the third month, the patients were again repeated the above mentioned measures.

General information

Acronym

IRCT registration information
IRCT registration number: **IRCT201012275483N1**
Registration date: **2011-01-28, 1389/11/08**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date
2011-01-28, 1389/11/08

Registrant information

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Recruitment status
Recruitment complete

Funding source
Aras International University

Expected recruitment start date
2010-04-18, 1389/01/29
Expected recruitment end date
2010-09-01, 1389/06/10
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of low calorie diet with and without sibutramine on metabolic syndrome risk factors and sonographic findings in non alcoholic fatty liver

Public title
The effect of sibutramine on non alcoholic fatty liver
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: non-alcoholic fatty liver disease, having 20 to 50 years old of both sexes, having BMI 30kg/m2 or more, willing to participate Exclusion criteria: Presence of thyroid disorders, diabetes, or uncontrolled hypertension, use of glucose, cholesterol, or triglyceride lowering drugs, estrogen or progesterone usage, supplementation of vitamin C, or E over the two months prior to the study,

menopausal women, smoking and alcohol use, being athletes

Age
From **18 years** old to **50 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethic Committee of Tabriz University of Medical Sciences

Street address
Tabriz University of Medical Sciences,Tabriz, Iran

City
Tabriz

Postal code

Approval date
2011-01-02, 1389/10/12

Ethics committee reference number
8949

Health conditions studied

1

Description of health condition studied
non alcoholic fatty liver

ICD-10 code
k70, k77

ICD-10 code description
Diseases of liver

Primary outcomes

1

Description
liver echogenicity

Timepoint
before and after intervention

Method of measurement
sonography

2

Description
weight

Timepoint
every two week

Method of measurement
Nestle scale

Secondary outcomes

1

Description
total cholestrol

Timepoint
at the beginning and end of the intervation

Method of measurement
enzymatic method with autoanalysis system

2

Description
lDL-C

Timepoint
at the beginning and end of the intervation

Method of measurement
enzymatic method with autoanalysis system

3

Description
HDL-C

Timepoint
at the beginning and end of the intervation

Method of measurement
enzymatic method with autoanalysis system

4

Description
Glucose

Timepoint
at the beginning and end of the intervation

Method of measurement
enzymatic method with autoanalysis system

5

Description
AST

Timepoint
at the beginning and end of the intervation

Method of measurement

ELISA

6

Description
ALT
Timepoint
at the beginning and end of the intervation
Method of measurement
spectrophotometery

7

Description
ferritin
Timepoint
at the beginning and end of the intervation
Method of measurement
ELISA

8

Description
HbA1c
Timepoint
at the beginning and end of the intervation
Method of measurement
ELISA

9

Description
Trigliceride
Timepoint
at the beginning and end of the intervation
Method of measurement
enzymatic method with autoanalysis system

Intervention groups

1

Description
Control group: vitamin E 400 IU supplement once daily and weight loss diet for 3 months
Category
Treatment - Drugs

2

Description
Intervention group: 15-mg capsule of sibutramine once a day half an hour before lunch and vitamin E supplement (400 IU) once a day and weight loss diet for 3 months
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Sheikhalrayis clinic
Full name of responsible person
Dr. Mehrangiz Ebrahimimamagani
Street address
Sheikhalrayis clinic, Golbad street
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
School of health & nutrition, Aras international university
Full name of responsible person
Mr. Farshidi
Street address
Tabriz University of Medical Sciences, Tabriz
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
School of health & nutrition, Aras international university
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty