

# 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

##### Name

Zahra Bahmanabadi

##### Name of organization / entity

School of health & nutrition -Aras International Unit

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8873 7757

##### Email address

ysf@aut.ac.ir

##### 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/m<sup>2</sup> 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

IDL-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 intervention

### Method of measurement

spectrophotometry

## 7

### Description

ferritin

### Timepoint

at the beginning and end of the intervention

### Method of measurement

ELISA

## 8

### Description

HbA1c

### Timepoint

at the beginning and end of the intervention

### Method of measurement

ELISA

## 9

### Description

Triglyceride

### Timepoint

at the beginning and end of the intervention

### 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

##### Name of organization / entity

School of health and nutrition, Aras International University

##### Full name of responsible person

Zahra Bahmanabadi

##### Position

student of master science on nutrition

##### Other areas of specialty/work

##### Street address

School of health and nutrition, Tabriz University of Medical Sciences

##### City

Tabriz

##### Postal code

##### Phone

+98 41 1335 7580

##### Fax

##### Email

bahmanabadi2009@gmail.com  
bahmanabadi2009@yahoo.com

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

School of health and nutrition

**Full name of responsible person**

Mehrangiz Ebrahimi Mamagani

**Position**

PH.D of nutrition epidemiology

**Other areas of specialty/work**

**Street address**

School of health and nutrition, Tabriz University of  
Medical Sciences

**City**

Tabriz

**Postal code**

**Phone**

+98 41 1335 7581

**Fax**

**Email**

ebrahimimamagani@tbzmed.ac.ir

**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

School of health@nutrition

**Full name of responsible person**

Zahra Bahmanabadi

**Position**

student of master science on nutrition

**Other areas of specialty/work**

**Street address**

School of health and nutrition, Tabriz University of  
Medical Sciences

**City**

Tabriz

**Postal code**

**Phone**

**Fax**

**Email**

bahmanabadi2009@gmail.com

**Web page address**

## 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*