

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

A comparative study of the effect of low calorie balanced diet versus low calorie high fiber diet on the hepatic transaminases, lipid profiles, insulin, glucose levels, blood pressure and anthropometric measurements of obese patients with nonalcoholic fatty liver disease (NAFLD)

Protocol summary

Summary

The aim of our study was to examine the changes in hypertransaminasemia after weight reduction in obese patients with nonalcoholic fatty liver disease (NAFLD) and the relation with insulin resistance. A convenient, clinical trials study with 3 months treatment period. 80 patients (men and women) aged 20-60 years old were selected among the patient referred to gastroenterology clinic of Motahary Center. Patients selection was based on BMI \geq 25 kg/m², ALT \geq 43 UI/L and NAFLD patient. A population of 80 obese patients with NAFLD was randomly allocated to two groups: a) diet I (low calorie high fiber diet, high-fibre (>15 g/1,000 kcal)) and b) diet II (low calorie balanced diet), dieting along 3 months. The two diets containing 18% protein, 28% fat and 55% carbohydrate. A fasting blood sample for measuring liver function tests were collected at the beginning and after 3 months consumption of two diets. At baseline and after 3 months, the index of ALT, AST, GGT, BT, total cholesterol, HDL-cholesterol, LDL-cholesterol, triglycerides, blood glucose, insulin and blood pressure will be measured.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201111218145N1**
Registration date: **2012-02-16, 1390/11/27**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-02-16, 1390/11/27

Registrant information

Name

Mousa Salehi

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, shiraz University of Medical Sciences

Expected recruitment start date

2011-12-22, 1390/10/01

Expected recruitment end date

2012-06-19, 1391/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study of the effect of low calorie balanced diet versus low calorie high fiber diet on the hepatic transaminases, lipid profiles, insulin, glucose levels, blood pressure and anthropometric measurements of obese patients with nonalcoholic fatty liver disease (NAFLD)

Public title

Comparison of weight loss diets on long-term

consequences of fatty liver disease in patients referred to the clinic Motahari Shiraz, 1390

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age 20-60; BMI>25; ALT>43 Exclusion criteria: Alcohol consumption; Hepatitis B; C; Cytomegalovirus; Epstein Barr infections; nonorgan-specific autoantibody hereditary defects (iron storage disease and copper; alpha-1 anti-trypsin deficiency)

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shiraz University of Medical Sciences

Street address

Zand Avenue, Central Medical Building, Shiraz

City

Shiraz

Postal code

PO Box 1978-71345

Approval date

2011-11-12, 1390/08/21

Ethics committee reference number

CT-905784

Health conditions studied

1

Description of health condition studied

Nonalcoholic fatty liver disease

ICD-10 code

K76

ICD-10 code description

Nonalcoholic steatohepatitis

Primary outcomes

1

Description

ALT

Timepoint

Before and 3 months after intervention

Method of measurement

Colorimetric method

2

Description

AST

Timepoint

Before and 3 months after intervention

Method of measurement

Colorimetric method

3

Description

GGT

Timepoint

Before and 3 months after intervention

Method of measurement

Colorimetric method

4

Description

Bilirubin total

Timepoint

Before and 3 months after intervention

Method of measurement

Colorimetric method

Secondary outcomes

1

Description

Insulin

Timepoint

Before and 3 months after intervention

Method of measurement

ELISA kit

2

Description

lipid profile

Timepoint

Before and 2 months after intervention

Method of measurement

Auto analyzer

3

Description

FBS

Timepoint

Before and 2 months after intervention

Method of measurement

Auto analyzer

4

Description

Body fat mass

Timepoint

Before and 3 months after intervention

Method of measurement

Body Composition Analyzer - Quad Scan 4000

5

Description

Blood pressure

Timepoint

Before and 3 months after intervention

Method of measurement

Mercury Barometer

6

Description

Weight

Timepoint

Before and 3 months after intervention

Method of measurement

Seca Scale

7

Description

Height, waist hip circumference

Timepoint

Before and 3 months after intervention

Method of measurement

Tape Meter

Intervention groups

1

Description

Receive a balanced low-calorie high-fiber diet for 3 months (reduction of 700 kcal daily intake and received more than 15 grams of fiber per 1,000 kcal according to the definition of high-fiber diet)

Category

Lifestyle

2

Description

Receive a balanced low-calorie diet for 3 months (reduction of 700 kcal daily intake and get as much as 14 grams of fiber per 1000 kcal intake according to the

definition of balanced diet)

Category

Lifestyle

Recruitment centers

1

Recruitment center**Name of recruitment center**

Shiraz Motahari Clinic

Full name of responsible person

Dr Seyed Kazem Hosseini Asl

Street address

Zand Avenue, Namazi Square, Motahari Clinic

City

Shiraz

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Vice chancellor for research, Shiraz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Ali Sahmedini

Street address

Zand Avenue, Central Medical Building

City

Shiraz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research, Shiraz University of Medical Sciences

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, Shiraz University of Medical Sciences

Full name of responsible person

Bayan Roohi

Position

MSc. student of nutrition

Other areas of specialty/work**Street address**

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Associate Professor

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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