

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Incidence of metabolic syndrome and the effect of the modified Mediterranean diet for prevention of metabolic syndrome in patients undergoing liver transplantation

Protocol summary

Summary

The aims of this study is to investigate the effects of modified Mediterranean diet on the incidence of Metabolic Syndrome after liver transplantation. Inclusion criteria: age over 18 exclusion criteria: age under 18; patient with any malignancy; multivisceral transplant; malignancy during stud. One hundred fifty adult elective liver transplantation recipients will enroll and divide into two groups: the control group (n = 85) and the standard diet (n = 65). Primary outcome time point will be 1, 2, 3 and 4 months after liver transplantation. We will measure: systolic and diastolic blood pressure, waist circumference; Metabolic Syndrome and serum levels of fasting blood glucose, triglycerides and others laboratory factors.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015012720841N1**

Registration date: **2015-02-12, 1393/11/23**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-02-12, 1393/11/23

Registrant information

Name

Seyed Jalil Masoumi

Name of organization / entity

Department of Clinical Nutrition, School of Nutrition and Food Sciences, Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice-Chancellery of Research and Technology, Shiraz University of Medical Sciences

Expected recruitment start date

2015-04-09, 1394/01/20

Expected recruitment end date

2016-09-20, 1395/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Incidence of metabolic syndrome and the effect of the modified Mediterranean diet for prevention of metabolic syndrome in patients undergoing liver transplantation

Public title

Effect of the modified Mediterranean diet for prevention of metabolic syndrome in patients undergoing liver transplantation

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: age over 18 exclusion criteria: age under 18; patient with any malignancy; multivisceral transplant; malignancy during study; Patients who do not want to cooperate

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample sizeTarget sample size: **150****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**

Ethics committee of Shiraz University of Medical Sciences

Street address

Vice-Chancellery of Research and Technology, Shiraz University of Medical Sciences

City

Shiraz

Postal code**Approval date**

2014-12-21, 1393/09/30

Ethics committee reference number

6554

Health conditions studied**1****Description of health condition studied**

Metabolic Syndrome

ICD-10 code

E78.1

ICD-10 code description

Pure hyperglyceridaemia

2**Description of health condition studied**

Metabolic Syndrome

ICD-10 code

I10

ICD-10 code description

Essential (primary) hypertension

3**Description of health condition studied**

Metabolic Syndrome

ICD-10 code

R73

ICD-10 code description

Elevated blood glucose level

4**Description of health condition studied**

Metabolic Syndrome

ICD-10 code

R63.5

ICD-10 code description

Abnormal weight gain

5**Description of health condition studied**

Metabolic Syndrome

ICD-10 code

E78.6

ICD-10 code description

Lipoprotein deficiency

Primary outcomes**1****Description**

Blood Pressure

Timepoint

Every 4 weeks till 16 weeks

Method of measurement

By a sphygmomanometer

2**Description**

Weight

Timepoint

Every 4 weeks till 16 weeks

Method of measurement

Iranian Rasa company scale

3**Description**

Waist circumference

Timepoint

Every 4 weeks till 16 weeks

Method of measurement

Meters of fabric

4**Description**

blood suger tests

Timepoint

Every 4 weeks till 16 weeks

Method of measurement

by an automated clinical chemistry analyzer

5

Description

Lipid profile (TG,CHOL,HDL-C,LDL-C)

Timepoint

Every 4 weeks till 16 weeks

Method of measurement

By an automated clinical chemistry analyzer

Secondary outcomes

empty

Intervention groups

1

Description

In treatment group, a MMD with some changes in its contents in response to Iranian dietary culture and adapted with anthropomorphic conditions for 16 weeks. This diet rich in whole grains, legumes, vegetables, fruits consumed in the diet of fat is olive oil and canola oil, daily consumption of white meat and red meat consumption will be weekly. The regime will use low-fat dairy and sugar consumption is extremely low.

Category

Prevention

2

Description

Control group will use diet and training routine that normally provided by the hospital nutritionists.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Organ Transplantation Center, Nemazee Hospital

Full name of responsible person

Seyed Jalil Masoumi

Street address

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-Chancellery of Research and Technology

Full name of responsible person

Seyed BasirHashemi

Street address

Vice-Chancellery of Research and Technology, Shiraz
University of Medical Sciences

City

Shiraz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice-Chancellery of Research and Technology

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

Department of Clinical Nutrition, School of Nutrition and Food Sciences, Shiraz University of Medic

Full name of responsible person

Seyed Jalil Masoumi

Position

Teacher

Other areas of specialty/work

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Person responsible for updating data

Contact

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Other areas of specialty/work
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Shiraz

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