

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

Effect of DASH diet on parameters of metabolic syndrome after liver transplantation

Protocol summary

Study aim

Investigating the effect of DASH diet on metabolic syndrome parameters in patients receiving liver transplantation

Design

Clinical trial with control group, parallel, Permuted block randomization (based on Random Allocation software), and Allocation concealment, on 96 patients receiving liver transplantation

Settings and conduct

Patients receiving liver transplants will be studied at Abu Ali Sina Hospital in Shiraz, Iran. One month after liver transplantation, the patient will be placed in one of the intervention groups (DASH diet) or control group (normal diet) for 6 months if the patient has the conditions to enter the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Receiving liver transplant 2. One month has passed since liver transplant surgery 3. Age over 18 years for both gender Exclusion criteria: 1. Having cardiovascular disease, kidney disease, diabetes, and cancer when entering the project 2. pregnancy during the project 3. The presence of cachexia in the patient 4. consume less than 80% of the recommended diet 5. Lack of willingness to cooperate in the study

Intervention groups

In the intervention group, DASH diet will be prescribed after calculating the calorie and macronutrient needs of the patient. In the control group, the usual diet (based on the Iranian food pyramid) will be used to measure the effectiveness of the DASH diet.

Main outcome variables

Waist circumference; fasting blood sugar; blood pressure; serum HDL; serum triglycerides; serum liver enzymes (AST, ALT)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190224042821N3**

Registration date: **2020-06-15, 1399/03/26**

Registration timing: **registered_while_recruiting**

Last update: **2020-06-15, 1399/03/26**

Update count: **0**

Registration date

2020-06-15, 1399/03/26

Registrant information

Name

Ali Barzegar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3335 7580

Email address

barzegarali@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-21, 1399/03/01

Expected recruitment end date

2021-02-19, 1399/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of DASH diet on parameters of metabolic syndrome after liver transplantation

Public title

Effect of DASH diet on liver transplantation

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

received liver transplant One month has passed since the liver transplant Age over 18 years for both gender

Exclusion criteria:

Having cardiovascular disease, kidney disease, diabetes, and cancer when entering the study Pregnancy during the study Having cachexia when entering the study Mental and physical problems that affect food intake Not following a recommended diet (less than 80% of the diet) Lack of willingness to cooperate in the study

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **96**

Randomization (investigator's opinion)

Randomized

Randomization description

The studied samples will be divided into intervention and control groups based on the Block Randomization method. This blocking will be done using "Random Allocation Software". In this program, after determining the number of samples and the number of groups studied (intervention and control), the "random block size" option will be used to determine the volume of each block, randomly. Finally, the program will arrange the samples to be intervened and control. To reduce bias and do allocation concealment, the samples list will be prepared and maintained by a person outside the study, and when each sample enters the study, the researcher will text him/her and about the role of the new sample (intervention Or control) will ask.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tabriz University of Medical

Sciences

Street address

Tabriz University of Medical Sciences, Attar Neyshabouri Ave, Golgasht Ave

City

Tabriz

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East Azarbaijan

Postal code

5166/1573113

Approval date

2020-04-20, 1399/02/01

Ethics committee reference number

IR.TBZMED.REC.1399.088

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

hyperglyceridemia

ICD-10 code

E78.1

ICD-10 code description

Pure hyperglyceridemia

2**Description of health condition studied**

hypertension

ICD-10 code

I10

ICD-10 code description

Essential (primary) hypertension

3**Description of health condition studied**

hyperglycemia

ICD-10 code

R73

ICD-10 code description

Elevated blood glucose level

4**Description of health condition studied**

Abnormal weight gain

ICD-10 code

E66.1

ICD-10 code description

Drug-induced obesity

5**Description of health condition studied**

liver transplant status

ICD-10 code

Z94.4

ICD-10 code description

Liver transplant status

6

Description of health condition studied

Decreased HDL-cholesterol level

ICD-10 code

E78.6

ICD-10 code description

Lipoprotein deficiency

Primary outcomes

1

Description

blood pressure

Timepoint

Once a month for 6 months

Method of measurement

Mercury barometer

2

Description

Weight

Timepoint

Once a month for 6 months

Method of measurement

digital scale

3

Description

waist circumference

Timepoint

Once a month for 6 months

Method of measurement

Meters of non-elastic fabric

4

Description

Blood sugar

Timepoint

Once a month for 6 months

Method of measurement

Automatic clinical chemical analysis device

5

Description

Lipid profile including TG, HDL-C

Timepoint

Once a month for 6 months

Method of measurement

Automatic clinical chemical analysis device

6

Description

Serum hepatic enzymes including AST and ALT

Timepoint

Once a month for 6 months

Method of measurement

Automatic clinical chemical analysis device

7

Description

Calorie intake

Timepoint

Once a month for 6 months

Method of measurement

24-hour dietary recall questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: will follow the DASH diet for 6 months. This diet is rich in whole grains, beans, vegetables, and fruits. The type of fat consumed in this diet is olive oil and canola. In this diet, white meat will be consumed daily and red meat will be consumed weekly. Low-fat dairy will be used in this diet.

Category

Prevention

2

Description

Control group: They will use a diet based on the Iranian food pyramid and routine training that is normally provided by hospital nutrition experts.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Abo-Ali Sina hospital

Full name of responsible person

Seyed Mohammad Hosein Borghei

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No 958, Boostan Blvd. Pastaran Blvd. Sadra new city.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mehrangiz Ebrahimi Mamaghani

Street address

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Email

ebrahimimamagani@tbzmed.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

Tabriz University of Medical science

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

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Ali Barzegar

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Participants' data will be analyzed and individual data will not be present.

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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

The following documents (after statistical analysis) will be published: * The main outcomes of the study (waist circumference, blood pressure, fasting blood sugar, blood triglycerides, blood HDL cholesterol, Blood liver enzymes (ALT, AST)) * Basic information (age, sex, height, weight, cause of liver disease)

When the data will become available and for how long

Start the access period: after publishing the results.

To whom data/document is available

All researchers

Under which criteria data/document could be used

With the permission of the authors of this article, the use of documentation is not prohibited.

From where data/document is obtainable

To receive the documents, send an e-mail to smhb.m74@gmail.com or borghei@tbzmed.ac.ir or call 00989378853125.

What processes are involved for a request to access data/document

With the permission of the authors of the study, the documents will be sent to the person in less than 1 week.

Comments