Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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
Province
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
Street address
No 958, Boostan Blvd. Pastaran Blvd. Sadra new city.
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Email
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Web page address
http://abualisina.net/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Mehrangiz Ebrahimi Mamaghani

Street address
Tabriz University of Medical Sciences, Gulgasht Street

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Tabriz

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East Azarbaijan

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6987512345

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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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Faculty of Nutrition and Food Sciences, Attar Neyshabouri Av., Golgasht St.

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Person responsible for scientific inquiries

Contact

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Full name of responsible person
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Person responsible for updating data

Contact

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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