Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of DASH diet on lipid profile in type 2 diabetic patients

Protocol summary

Summary

This study is a randomized clinical trial wlich will be conducted aiming at examining the effect of DASH diet (dietary approaches to stop hypertension) on lipid profile, blood pressure, and body composition in patients aged between 18-65 suffering from diabetes type 2 who refer to Professional clinic of Urmia city within 12 weeks interventions. Those who suffer from diabetes type 2 and consume glibenclamide or metformin, and Not Suffering from any diabetic complications, will be included in this study by completing the consent form. Criteria for exclusion from the study include suffering from diabetes type 1, insulin therapy, etc.80 people are randomly selected and are then classified into 2 groups, Intervention group receiving DASH diet and control group receiving diabetic diet in accordance with the ADA (American Diabetes Association) recommendations. Blinding will be carried out for people collecting the information and perform biochemical experiments. 24-hour dietary recalls in three days (Two working days and a holiday) and analysis with N4 (nutritionist 4) software to monitor the participants diet, blood sampling to lipid profile biochemical tests, BIA (Bioelectrical impedance analysis) to body composition analysis, also international physical activity questionnaire to control the physical activity of participants in the study will be performed at the beginning and end of intervention. It will be used for the patients in case of any possible positive effect in those suffering diabetes type 2.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017021432571N1**
Registration date: **2017-05-28, 1396/03/07**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-05-28, 1396/03/07

Registrant information

Name
Majid Manafi
Name of organization / entity
Urmia University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 32770698
Email address
manafi.m@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

researcher (Reza Hashemi)

Expected recruitment start date

2016-01-20, 1394/10/30

Expected recruitment end date

2016-04-19, 1395/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of DASH diet on lipid profile in type 2 diabetic patients

Public title

The effect of the DASH diet in patients with type 2 diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Criteria for inclusion in the study: Suffering from diabetes type 2; Not Suffering from any diabetic complications

such as nephropathy, retinopathy, neuropathy and cardiovascular complications; Aged between 18 to 65; Consumption of same drugs (glibenclamide, metformin). Criteria for exclusion from the study: Suffering from diabetes type 1; Insulin Therapy; Suffering from liver diseases; Suffering from renal diseases; Suffering from thyroid disease; Pregnancy and lactation; Smoking and drinking alcohol; Consumption of drugs reducing blood fat and pressure and Weight, thiazide diuretics and corticosteroids; Change of type and dosage of consuming drugs during the study; Consumption of Herbal or chemical supplements; Suffering from Electrolyte abnormalities and Digestive diseases associated with malabsorption; Gastric bypass surgery and cholecystectomy.

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
N/A

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
During the study, patients have a constant physical activity.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
ethics Committee of Urmia University of Medical Sciences

Street address
Nutrition Department, Faculty of Medicine, College of Medicine, Urmia University of Medical Science, 11th km of Nazloo Road, Urmia

City
Urmia

Postal code

Approval date
2015-11-23, 1394/09/02

Ethics committee reference number
umsu.rec.1394-01-32-1919

Health conditions studied

1

Description of health condition studied
Diabetes mellitus

ICD-10 code
E11

ICD-10 code description
Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description
Total cholesterol

Timepoint
Before Intervention and 12 weeks after Intervention

Method of measurement
enzymatic method, mg/dl

2

Description
Triglyceride

Timepoint
Before Intervention and 12 weeks after Intervention

Method of measurement
enzymatic method, mg/dl

3

Description
HDL cholesterol

Timepoint
Before Intervention and 12 weeks after Intervention

Method of measurement
enzymatic method, mg/dl

4

Description
LDL cholesterol

Timepoint
Before Intervention and 12 weeks after Intervention

Method of measurement
enzymatic method, mg/dl

5

Description
VLDL cholesterol

Timepoint
Before Intervention and 12 weeks after Intervention

Method of measurement
Triglyceride/5, if TG>400: VLDL-C = TC – (HDL-C + LDL-C), mg/dl

6

Description
Free Fatty Acid

Timepoint
Before Intervention and 12 weeks after Intervention
Method of measurement
ELISA method, nmol/ml

7

Description
Weight
Timepoint
Before Intervention and 12 weeks after Intervention
Method of measurement
Inbody770 Body Analyzer, kg

Secondary outcomes

1

Description
Systolic blood pressure
Timepoint
Before Intervention and 12 weeks after Intervention
Method of measurement
Mercury sphygmomanometer, mmHg

2

Description
Diastolic blood pressure
Timepoint
Before Intervention and 12 weeks after Intervention
Method of measurement
Mercury sphygmomanometer, mmHg

3

Description
Body composition analysis (Fat mass, Fat free mass, Body water, Body cell mass, Skeletal muscle mass)
Timepoint
Before Intervention and 12 weeks after Intervention
Method of measurement
Inbody770 Body Analyzer, Bioelectrical impedance analysis

Intervention groups

1

Description
The intervention group will be adherence to DASH diet for a period of 12 weeks.
Category
Prevention

2

Description
The control group will be adherence to American Diabetes Association recommendations for a period of 12 weeks.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Nutrition counseling clinic and diet therapy
Full name of responsible person
Reza Hashemi
Street address
Floor 2, Imam Khomeini Hospital professional clinic (1), Ershad Ave
City
urmia

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Urmia University of Medical Sciences
Full name of responsible person
Reza Hashemi
Street address
Nutrition counseling office and diet therapy,Imam Khomeini Hospital, Ershad Ave
City
Urmia
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Urmia 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
Urmia University of Medical Sciences
Full name of responsible person
Majid Manafi
Position
Master of Science in Nutritional Science/ Faculty Member
Other areas of specialty/work
Street address

Nutrition Department, Faculty of Medicine, College of Medicine, Urmia University of Medical Science, 11th km of Nazloo Road

City
Urmia

Postal code
5715799313

Phone
+44 1278803

Fax
+98 44 3278 0801

Email
majidmanafi@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Urmia University of Medical Sciences

Full name of responsible person
Majid Manafi

Position
Master of Science in Nutritional Science/ Faculty Member

Other areas of specialty/work

Street address
Nutrition Department, Faculty of Medicine, College of Medicine, Urmia University of Medical Science, 11th km of Nazloo Road

City
Urmia

Postal code
5715799313

Phone
+98 44 1278 0803

Fax
+98 44 3278 0801

Email
majidmanafi@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Urmia University of Medical Science

Full name of responsible person
Majid Manafi

Position
Master of Science in Nutritional Science/ Faculty Member

Other areas of specialty/work

Street address
Nutrition Department, Faculty of Medicine, College of Medicine, Urmia University of Medical Science, 11th km of Nazloo Road

City
Urmia

Postal code
5715799313

Phone
+98 44 1278 0803

Fax
+98 44 3278 0801

Email
majidmanafi@yahoo.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