Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Jul 2026

Evaluating the effect of replacing clarified butter with canola oil on Metabolic Syndrome components, fatty liver index, and insulin resistance in patients with Metabolic Syndrome

Protocol summary

Study aim

Determining the effects of replacing clarified butter with canola oil on Metabolic Syndrome components, fatty liver index, and insulin resistance in patients with Metabolic Syndrome

Design

Before and After clinical trial, one intervention group, 42 patients

Settings and conduct

The present study is the effect of canola oil in the treatment of metabolic syndrome, conducted at the liver and gastrointestinal clinic of Imam Khomeini hospital in Urmia city. The study involved replacing the clarified butter consumed by individuals with canola oil, and providing in-person and telephone counseling and educational materials on healthy nutrition and physical activity.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Having metabolic syndrome according to International Diabetes Federation (IDF) guideline Age range from 35 to 65 years Daily clarified butter consumption of 3 to 8 servings Exclusion criteria: Renal disease Heart failure Having various type of cancer Psychotic disorders Pregnancy and lactation during the study

Intervention groups

Individuals will be selected who consume ghee or clarified butter for cooking, with a daily consumption of 3 to 8 units of this oil. In addition to the usual treatment, All individuals will be advised to replace clarified butter with the same amount of canola oil.To ensure compliance with recommendations and to examine food groups and physical activity during the study, a 24-hour recall questionnaire will be completed for three days (two non-holiday days and one holiday) and a physical activity questionnaire before the start of the study and at the end of each month during the study. Also, patients will be contacted by phone every week and necessary reminders will be given.

Main outcome variables

Metabolic Syndrome components; Insulin resistance; Fatty Liver Index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170206032417N6**
Registration date: **2023-06-18, 1402/03/28**
Registration timing: **prospective**

Last update: **2023-06-18, 1402/03/28**
Update count: **0**

Registration date

2023-06-18, 1402/03/28

Registrant information

Name

Mohammad Alizadeh

Name of organization / entity

Urmia University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 44 3275 2375

Email address

alizadeh.m@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-06, 1402/04/15

Expected recruitment end date

2023-08-23, 1402/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluating the effect of replacing clarified butter with canola oil on Metabolic Syndrome components, fatty liver index, and insulin resistance in patients with Metabolic Syndrome

Public title
Effect of type oil in treatment of Metabolic syndrome

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Having metabolic syndrome according to International Diabetes Federation (IDF) guideline Age range from 35 to 65 years Daily clarified butter/ghee consumption of 3 to 8 servings

Exclusion criteria:
Renal disease Heart failure Having various type of cancer Psychotic disorders Pregnancy and lactation during the study

Age
From **35 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **42**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

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

Street address
Orjhans Street, Resalat Blvd, Urmia University of Medical Sciences

City
Urmia

Province
West Azarbaijan

Postal code
5714783734

Approval date
2023-01-15, 1401/10/25

Ethics committee reference number
IR.UMSU.REC.1401.359

Health conditions studied

1

Description of health condition studied
Metabolic syndrome

ICD-10 code
E88.81

ICD-10 code description
سندرم متابولیک

Primary outcomes

1

Description
Fasting blood sugar

Timepoint
Measurement of fasting blood sugar at the beginning of the study (before the intervention) and 12 weeks (after the intervention) after the start of canola oil consumption.

Method of measurement
Enzymatic method, IU/ Lit

2

Description
Waist circumference

Timepoint
Measurement of waist circumference at the beginning of the study (before the intervention) and 12 weeks (after the intervention) after the start of canola oil consumption.

Method of measurement
Meter, Cm

3

Description
HDL cholesterol

Timepoint
Measurement of HDL cholesterol at the beginning of the study (before the intervention) and 12 weeks (after the intervention) after the start of canola oil consumption.

Method of measurement
Enzymatic method, mg/dl

4

Description
Triglyceride
Timepoint
Measurement of Triglyceride at the beginning of the study (before the intervention) and 12 weeks (after the intervention) after the start of canola oil consumption.
Method of measurement
Enzymatic method, mg/dl

5

Description
Systolic blood pressure
Timepoint
Measurement of Systolic blood pressure at the beginning of the study (before the intervention) and 12 weeks (after the intervention) after the start of canola oil consumption.
Method of measurement
Sphygmomanometer, mm Hg

6

Description
Diastolic blood pressure
Timepoint
Measurement of Diastolic blood pressure at the beginning of the study (before the intervention) and 12 weeks (after the intervention) after the start of canola oil consumption.
Method of measurement
Sphygmomanometer, mm Hg

Secondary outcomes

1

Description
Weight
Timepoint
Measurement of weight at the beginning of the study (before the intervention) and 12 weeks (after the intervention) after the start of canola oil consumption.
Method of measurement
Scale. kg

2

Description
Body mass index
Timepoint
Measurement of BMI at the beginning of the study (before the intervention) and 12 weeks (after the intervention) after the start of canola oil consumption.
Method of measurement
Weight(kg)/[height(m)]2 , kg/m2

3

Description
Gamma Glutamyl transferase
Timepoint
Measurement of GGT at the beginning of the study (before the intervention) and 12 weeks (after the intervention) after the start of canola oil consumption.
Method of measurement
Enzymatic method , IU/ Lit

4

Description
Serum insulin
Timepoint
Measurement of Serum insulin at the beginning of the study (before the intervention) and 12 weeks (after the intervention) after the start of canola oil consumption.
Method of measurement
Radioimmunoassay

5

Description
low-density lipoprotein cholesterol
Timepoint
Measurement of LDL at the beginning of the study (before the intervention) and 12 weeks (after the intervention) after the start of canola oil consumption.
Method of measurement
Enzymatic method, mg/dl

6

Description
Total cholesterol
Timepoint
Measurement of Total cholesterol at the beginning of the study (before the intervention) and 12 weeks (after the intervention) after the start of canola oil consumption.
Method of measurement
Enzymatic method, mg/dl

7

Description
Homeostasis model assessment-insulin resistance
Timepoint
Measurement of HOMA-IR at the beginning of the study (before the intervention) and 12 weeks (after the intervention) after the start of canola oil consumption.
Method of measurement
HOMA-IR = [(Fasting Serum Glucose, mmol/L) × Fasting Serum Insulin, µIU/mL)] / 22.5

8

Description
Height
Timepoint
Measurement of Height at the beginning of the study (before the intervention)
Method of measurement
Stadiometer- cm

9

Description
Quantitative insulin sensitivity check index
Timepoint
Measurement of QUICKI at the beginning of the study (before the intervention) and 12 weeks (after the intervention) after the start of canola oil consumption.
Method of measurement
QUICKI =[1 / (log(Fasting Insulin) + log(Fasting Glucose))]

10

Description
Fatty liver index
Timepoint
Measurement of FLI at the beginning of the study (before the intervention) and 12 weeks (after the intervention) after the start of canola oil consumption.
Method of measurement
FLI= [e0.953 × loge (TC) + 0.139 × BMI + 0.718 × loge (GGT) + 0.053 × WC - 15.745] ÷ 1+ [e0.953 × loge (TC) + 0.139 × BMI + 0.718 × loge (GGT) + 0.053 × WC - 15.745] × 100

Intervention groups

1

Description
Initially, individuals will be selected who consume ghee or clarified butter for cooking, with a daily consumption of 3 to 8 units of this oil. In addition to the usual treatment, all individuals will be advised to switch to the same amount of canola oil they used for cooking. To ensure uniform consumption of other food groups in individuals, everyone will be advised to follow the Food and Agriculture Organization (FAO) recommendations for Iranians. All participants will be asked not to change their physical activity and medication during the study. The dosage of medications (vitamin E and pioglitazone) will be the same for all individuals from the beginning to the end of the study. To ensure compliance with recommendations and to examine food groups and physical activity during the study, a 24-hour recall questionnaire will be completed for three days (two non-holiday days and one holiday) and a physical activity questionnaire before the start of the study and at the end of each month during the study, totaling 12 questionnaires for the dietary recall and 4 days for the physical activity questionnaire during the study. Also, patients will be contacted by phone every week and necessary reminders will be given. The counseling program for patients will include one in-person counseling session, provision of educational materials, and relevant text messages. The duration of intervention is 12 weeks.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Teaching Hospital, Urmia
Full name of responsible person
Dr. Mohammad Reza mohammad hosseini azar
Street address
Ershad Blvd, Ayatollah Modarres Blvd, Urmia
City
Urmia
Province
West Azarbaijan
Postal code
5431234567
Phone
+98 44 3567 8549
Email
hosseiniazar@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Dr Saber gholizadeh
Street address
Orjhans Street, Resalat Blvd, Urmia
City
Urmia
Province
West Azarbaijan
Postal code
5714783734
Phone
+98 21 8753 2210
Email
saber@umsu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Oroumia University of Medical Sciences
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
Oroumia University of Medical Sciences

Full name of responsible person
Dr. Mohammad Alizadeh

Position
Professor in Nutrition

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

Street address
Department of Nutrition, School of Medicine, Urmia University of Medical Science, 11th km of Nazloo Highway, Urmia

City
Urmia

Province
West Azarbaijan

Postal code
5715799313

Phone
+98 44 3275 2375

Email
alizadeh.m@umsu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Oroumia University of Medical Sciences

Full name of responsible person
Dr. Mohammad Alizadeh

Position
Ph.D in Nutrition/ Professor in Urmia University of Medical Sciences

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

Street address
Department of Nutrition, School of Medicine, Urmia University of Medical Science, 11th km of Nazloo Highway, Urmia

City
Urmia

Province
West Azarbaijan

Postal code
5315799313

Phone
+98 44 3275 2375

Email
alizadeh.m@umsu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Oroumia University of Medical Sciences

Full name of responsible person
Fatemeh Maleki Sedgi

Position
MSc Student of nutrition

Latest degree
Bachelor

Other areas of specialty/work
Nutrition

Street address
Department of Nutrition, School of Medicine, Urmia University of Medical Science, 11th km of Nazloo Highway, Urmia

City
Urmia

Province
West Azarbaijan

Postal code
5715799313

Phone
+98 44 3275 2375

Email
F.maleki1998@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

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

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

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

Clinical Study Report
Undecided - It is not yet known if there will be 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