

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

Effects of Extra Virgin Olive Oil on Serum Hepatic enzymes ,Insulin resistance, Lipoproteins, TNF α , Anthropometric measurments and Esteatosis severity in Non - alcoholic Fatty Liver Patients Whit Loss Weight Diet

Protocol summary

Summary

main objective of this study is to investigate Effects of Extra Virgin Olive Oil on Serum TNF α , Hepatic enzymes(ALT , AST) ,Lipoproteins, ,Insulin resistance, , Anthropometric measurments and Esteatosis severity in Non - alcoholic Fatty Liver Patients and Loss Weight Diet . In this clinical trial, men and women (n=50), aged 20-60 years old who referred to clinics of mazandaran university of medical sciences in sari ,will be randomly assigned into olive oil(receiving the equivalent of 20% of total daily energy requirement from olive oil) or control group (receiving their usual consumption of oil)for 12 weeks.10 days before the start of intervention patients will be asked not to consume olive oil . All the patients in both groups will receive a hypo caloric diet for 90 days according to their weight, age and sex .information about anthropometric measurments (weight , waist circumference ,BMI , percent body fat) and three - day 24 hour dietary recall will beobtained at the beginning of the study and the end of each month. physical activity , serum TNF α , liver enzymes (ALT,AST),lipoproteins profile, fasting glucose, insulin resistance and Esteatosis severity will be determined at the baseline and after 12 weeks

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201111022709N20**
Registration date: **2011-12-26, 1390/10/05**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-12-26, 1390/10/05

Registrant information

Name

Farzad Shidfar

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tehran university of medical sciences

Expected recruitment start date

2011-11-22, 1390/09/01

Expected recruitment end date

2012-05-21, 1391/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Extra Virgin Olive Oil on Serum Hepatic enzymes ,Insulin resistance, Lipoproteins, TNF α , Anthropometric measurments and Esteatosis severity in Non - alcoholic Fatty Liver Patients Whit Loss Weight Diet

Public title

" effects of Olive Oil in non-alcoholic fatty liver disease

patients"

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion Criteria: signing written informed consent, age between 20 and 60, diagnosis of non-alcoholic fatty liver disease by fatty infiltration on ultrasound and abnormal serum liver function tests (AST or ALT > 30 u/l in men and > 20 in women), no smoking, BMI between 25 to 35, no pregnancy or lactation, no use of dietary supplements 2 month prior to enrollment, not having diabetes, , acute heart disease, , other form of liver disease (viral or autoimmune hepatitis, metabolic and hereditary liver disease), no usual use of Olive Oil in dietary pattern, no use of drugs that induces steatosis (amidarone, methotrexate, systemic glucocorticoid, tetracycline, tamoxifen, estrogen, anabolic steroids, valporic acid) , no use of Lipid lowering drugs . Exclusion Criteria: those who are not interested in participating in the study, start using drugs affecting liver function, failure to complete or correct use of Olive Oil according to the instruction given , change in recommended diet and daily physical activity

Age
From **20 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Faculty of Public Health of Tehran University of
Medical Sciences

Street address

Number 60, Alvand street, Argentina square, Tehran

City

TEHRAN

Postal code

Approval date

2011-09-23, 1390/07/01

Ethics committee reference number

130,1872,90 ص

Health conditions studied

1

Description of health condition studied

non-alcoholic fatty liver

ICD-10 code

k76.0

ICD-10 code description

Fatty (change of) liver , not elsewhere classified

Primary outcomes

1

Description

serum ALT

Timepoint

BEFORE AND END OF INTERVENTION

Method of measurement

IFCC,IU/D

2

Description

Sserum AST

Timepoint

BEFORE AND END OF INTERVENTION

Method of measurement

IFCC,IU/D

3

Description

steatosis severity

Timepoint

BEFORE AND END OF INTERVENTION

Method of measurement

Sonography

Secondary outcomes

1

Description

TNF α

Timepoint

BEFORE AND END OF INTERVENTION

Method of measurement

ELISA5,Pg/L

2

Description

fasting TG

Timepoint

BEFORE AND END OF INTERVENTION

Method of measurement
enzymetic method , mg / dl

3

Description
insulin resistance

Timepoint
BEFORE AND END OF INTERVENTION

Method of measurement
calculation

4

Description
fasting insulin

Timepoint
BEFORE AND END OF INTERVENTION

Method of measurement
Immunoassay radiometer,MU / ml

5

Description
fastingGlucose

Timepoint
BEFORE AND END OF INTERVENTION

Method of measurement
Colorimetric method.mg / dl

6

Description
HDL - C

Timepoint
BEFORE AND END OF INTERVENTION

Method of measurement
enzymetic method , mg / dl

7

Description
LDL - C

Timepoint
BEFORE AND END OF INTERVENTION

Method of measurement
enzymetic method , mg / dl

8

Description
Total cholestrol

Timepoint
BEFORE AND END OF INTERVENTION

Method of measurement
enzymetic method , mg / dl

9

Description
percent body weight

Timepoint
BEFORE AND END OF INTERVENTION

Method of measurement

Caliper, percent

10

Description
BMI

Timepoint
BEFORE AND END OF INTERVENTION

Method of measurement
calculation,Kg / m2

11

Description
waist circumference

Timepoint
BEFORE AND END OF INTERVENTION

Method of measurement
TAPE , Cm

Intervention groups

1

Description
intervention group :Extra Virgin Olive Oil, 20% of total daily energy requirement olive will be replaced with usual daily consumption of oil for every patients for 12 weeks

Category
Treatment - Other

2

Description
control group :(not application)20% of total daily energy requirement from usual daily consumption of oil for 12 weeks

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam KHomeini therapeutic educational center

Full name of responsible person

Dr Tarang Taghvai, Professor of mazandaran university of medical sciences,Gastroenterologist

Street address

Sari- Amir mazandarani street. Emam KHomeini Hospital

City

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Research, Tehran University of
Medical Sciences

Full name of responsible person

Dr Akbar Fottohi

Street address

Keshavarz Bld - intersection of Qods street

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice-chancellor for Research, Tehran 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

Email

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Faculty of Public Health of Tehran University of
Medical Sciences

Full name of responsible person

Dr Farzad Shidfar

Position

Professor /nutrition PhD

Other areas of specialty/work**Street address**

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Medical Sciences

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Fax**Person responsible for updating data****Contact****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