Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Nov 2026

Effects of Extra Virgin Olive Oil on Serum Hepatic enzymes ،Insulin resistance، Lipoproteins، TNFα ، 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 TNFα , 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 TNFα, 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

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Farzad Shidfar
Name of organization / entity
Iran University of Medical Sciences
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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، TNFα ، 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 20and 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 functiont, 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

Person responsible for general inquiries

Contact
Name of organization / entity
Faculty of Public Health of Tehran University of Medical Sciences
Full name of responsible person
Dr Farzad Shidfar
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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