Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Nov 2026

The investigation of the effects of Capparis Spinosa Fruit pickle (Traditional Iranian Medicine product) on Liver Transaminases in Nonalcoholic Fatty Liver Disease (NFLD)

Protocol summary

Summary

This study aims to investigate the effect of the Capparis Spinosa Fruit pickle (Traditional Iranian Medicine product) on 1) Liver Enzymes, 2) Lipid Profile, 3) Insulin Resistance, 4) Body Mass Index, 5) appetite, 6) cs-CRP among nonalcoholic fatty liver disease patients. The total sample was 50 people, which included the two intervention and control groups (25 people each). Using the Random number table,the samples were divided into the two intervention and control groups. The study was not blinded. Inclusion criteria: nonalcoholic fatty liver (elevated SGPT and sonography results); age 12 to 80 years. Exclusion criteria: Hyperlipidemia during treatment or Severe hyperlipidemia; pregnancy and lactation; Coagulopathies; thyroid disease; cirrhosis, viral hepatitis; Overt diabetes; Drugs that affect metabolism or liver enzyme levels such as OCP, Corticosteroid, etc; patients who are hospitalized in the course of treatment and therefore could not continue the treatment; patients who cannot eat pickled capers fruit for various reasons; Patients who cannot adhere to the guidelines recommended in the lifestyle training. Variables are liver enzymes, lipid profile, insulin resistance, body mass index, appetite, cs-CRP. Interventions included: a training course in lifestyle which offers a training package to both groups, daily consumption of 40 grams of Capparis Spinosa fruit pickle (only offered to the intervention group) for 12 weeks.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015122425686N1**
Registration date: **2016-05-10, 1395/02/21**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2016-05-10, 1395/02/21

Registrant information

Name

Narjes Khavasi

Name of organization / entity

Tabriz University of Medical and Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 3337 9521

Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2016-03-10, 1394/12/20

Expected recruitment end date

2016-10-21, 1395/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The investigation of the effects of Capparis Spinosa Fruit pickle (Traditional Iranian Medicine product) on Liver Transaminases in Nonalcoholic Fatty Liver Disease (NFLD)

Public title
Effects of the Capparis pickle on Fatty Liver
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: nonalcoholic fatty liver (elevated SGPTand sonography results); age 12 to 80 years. Exclusion criteria: Hyperlipidemia during treatment or Severe hyperlipidemia; pregnancy and lactation; Coagulopathies; thyroid disease; cirrhosis, viral hepatitis; Overt diabetes; Drugs that affect metabolism or liver enzyme levels such as OCP, Corticosteroid, ..; patients who are hospitalized in the course of treatment and therefore could not continue the treatment; patients who cannot eat pickled capers fruit for various reasons; Patients who cannot adhere to the guidelines recommended in the lifestyle training.
Age
From **12 years** old to **80 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
Ethics Committee of Tabriz University of Medical Sciences
Street address
No 2 Central Building, Tabriz University of Medical Sciences, University Street, Tabriz,Iran
City
Tabriz
Postal code
5165665931
Approval date
2015-10-26, 1394/08/04
Ethics committee reference number
TBZMED.REC.1394.650

Health conditions studied

1

Description of health condition studied
Nonalcoholic fatty liver disease
ICD-10 code
k76.0
ICD-10 code description
Nonalcoholic fatty liver disease (NAFLD)

Primary outcomes

1

Description
SGPT
Timepoint
Before the intervention, the end of the twelfth week intervention
Method of measurement
Blood sample

2

Description
SGOT
Timepoint
Before the intervention, the end of the twelfth week intervention
Method of measurement
Blood sample

Secondary outcomes

1

Description
Total chlo
Timepoint
Before the intervention, the end of the twelfth week intervention
Method of measurement
Blood sample

2

Description
FBS
Timepoint
Before the intervention, the end of the twelfth week intervention
Method of measurement
Blood sample

3

Description
TG
Timepoint
Before the intervention, the end of the twelfth week intervention

Method of measurement
Blood sample

4

Description
VLDL
Timepoint
Before the intervention, the end of the twelfth week intervention
Method of measurement
Blood sample

5

Description
LDL
Timepoint
Before the intervention, the end of the twelfth week intervention
Method of measurement
Blood sample

6

Description
HDL
Timepoint
Before the intervention, the end of the twelfth week intervention
Method of measurement
Blood sample

7

Description
Fasting Insulin
Timepoint
Before the intervention, the end of the twelfth week intervention
Method of measurement
Blood sample

8

Description
cs-CRP
Timepoint
Before the intervention, the end of the twelfth week intervention
Method of measurement
Blood sample

9

Description
BMI
Timepoint
Before the intervention, the end of the twelfth week intervention
Method of measurement
Digital weighing scales and measuring the height of meters

10

Description
Appetite
Timepoint
Before the intervention, the end of the twelfth week intervention
Method of measurement
VAS Questionnaire

11

Description
Insulin resistance
Timepoint
Before the intervention, the end of the twelfth week intervention
Method of measurement
HOMA Index

Intervention groups

1

Description
Intervention 1 : the intervention group In addition to teaching life style and training package similar at baseline and follow up with phone calls weekly, daily intake of 40 mg pickled capers fruit with meals for lunch and dinner
Category
Treatment - Drugs

2

Description
Intervention 2: teaching life style and training package similar at baseline and follow up with phone calls weekly in the control group
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Zanjan Metabolic Disease Reserch Center
Full name of responsible person
Narjes Khavasi
Street address
Zanjan Metabolic Diseases Research Center, Hazrat Vali-Asr hospital, Zanjan,Iran
City
Zanjan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Tabriz University of Medical Sciences
Full name of responsible person
Narjes khavas
Street address
Central Building, Tabriz University of Medical Sciences, University Street, Tabriz
City
Tabriz
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, Tabriz 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
Tabriz University of Medical and Sciences
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Narjes.Khavasi
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PhD student of traditional medicine
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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