

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 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

khavasin@tbzmed.ac.ir

##### 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 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, ..; 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

**Full name of responsible person**

Narjes.Khavasi

**Position**

PhD student of traditional medicine

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

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**Full name of responsible person**

Mohamad Hosein Somi

**Position**

Professor, Subspecialty of Gastroenterology and  
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**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*