

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Determine effect of weight loss on serum level of inflammatory cytokines in obese patients with fatty liver disease

Protocol summary

Summary

Our aim in this study is to determine effect of weight loss on serum levels of inflammatory cytokines (High sensitivity C-Reactive protein, Tumor necrosis factor alpha, Interleukin Six and One) in obese patients with fatty liver disease. In a uni-central clinical trial, 40 patients from both genders and with Body Mass Index equal or greater 30, fulfilling inclusion criteria will be enrolled in this study and admitted to the fatty liver clinic of Emam Reza Hospital, Tabriz, Iran. They will receive 8 weeks of calorie restricted, weight loss diet. Serum levels of inflammatory cytokines (above) before and just after calorie restricted regimen with 5 cc blood sampling and by ELISA method in each stage will be measured and compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014030515105N2**

Registration date: **2014-03-31, 1393/01/11**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-03-31, 1393/01/11

Registrant information

Name

Farahnoosh Farnood

Name of organization / entity

Tabriz University of Medical Science

Country

Iran (Islamic Republic of)

Phone

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Email address

naghavim@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2013-12-31, 1392/10/10

Expected recruitment end date

2014-03-01, 1392/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determine effect of weight loss on serum level of inflammatory cytokines in obese patients with fatty liver disease

Public title

Effect of weight loss on inflammatory indicators in obese patients with fatty liver disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: (Diagnosis of fatty liver disease according to increased liver enzymes and report of sonography; Body mass index equal or greater than 30; Agreement to participate in the study; Obedience to regimen) Exclusion criteria: (Metabolic or systemic inflammatory diseases; Diabetes mellitus; Ongoing use of anti inflammatory, Immunosuppressive or metabolism affecting medications, Weight or appetite loss medications; Pregnancy; Breast feeding; Daily smoking; Disobedience to regimen)

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

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 Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences, Daneshgah Sq.

City

Tabriz

Postal code

Approval date

2014-03-01, 1392/12/10

Ethics committee reference number

92214

Health conditions studied

1

Description of health condition studied

Fatty liver

ICD-10 code

K76.0

ICD-10 code description

Fatty (change of) liver

Primary outcomes

1

Description

Weight

Timepoint

Before and just after intervention

Method of measurement

Use same scale and according to Kilogram

Secondary outcomes

1

Description

High sensitivity C- Reactive protein

Timepoint

Before and just after intervention

Method of measurement

Elisa according to Nanogram per milliliter

2

Description

Tumor necrosis factor alpha

Timepoint

Before and just after intervention

Method of measurement

Elisa according to Picogram per milliliter

3

Description

Interleukin-1beta

Timepoint

Before and just after intervention

Method of measurement

Elisa according to Picogram per milliliter

4

Description

Interleukin-6

Timepoint

Before and just after intervention

Method of measurement

Elisa according to Picogram per milliliter

Intervention groups

1

Description

low calorie diet

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatty liver clinic, Emam Reza Hospital

Full name of responsible person

Kamal Boostani

Street address

Endoscopy ward, Emam Reza Hospital, Golgasht Ave.

City
Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tabriz University of Medical Sciences

Full name of responsible person

AliReza Ostad Rahimi

Street address

Vice chancellor for research, Tabriz University of Medical Sciences, Daneshgah Avenue, Daneshgah Square

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 Sciences

Full name of responsible person

Kamal Boostani

Position

Internist/ Student of Gastroenterology& Hepatology

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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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