

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Studying the effect of weight loss through calorie restricted diet on apoptotic factor levels of cytokeratin 18 and indicators of liver dysfunction in patients with non-alcoholic steatohepatitis (NASH)

Protocol summary

Summary

The aim of this study is to evaluate the effect of weight loss on the levels of the cytokeratin 18 apoptotic marker, liver dysfunction factors, and fibrosis and hepatic steatosis detected by fibroscopy. The population of the study is consisted of 60 people who were selected from non-alcoholic liver patients referring to Apadana Clinic based on entry and exit criteria or simple random method. Entrance criteria: BMI 25-40, liver fibrosis 2 and higher, liver enzymes 1.5 fold. Exit criteria: Viral hepatitis, the use of toxic liver drugs, taking alcohol and other liver diseases. This intervention has no control group as well as placebo. The intervention involves receiving a calorie-restricted diet of 500 kcal (individuals with a BMI of 25-30) and 1000 kcal (individuals with a BMI of 35-40) that should be followed for 6 consecutive months. Biochemical tests, as well as 24-hour recall, record anthropometric measurements for all patients are done at beginning of intervention and 3 and 6 months after the intervention. Six months after the intervention, cytokeratin 18 levels are measured by the ELISA kit in frozen serum samples. Patients will be referred to Apadana Clinic to perform fibroscopy to assess the effect of diet and weight loss on liver steatosis and fibrosis.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017081535707N1**
Registration date: **2017-10-15, 1396/07/23**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-10-15, 1396/07/23

Registrant information

Name

Sepideh Mohammadpour

Name of organization / entity

Nutrition group. Medicine faculty. Mashhad university of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 38828888051

Email address

mohammadps941@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad university of Medical Science

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2017-11-22, 1396/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Studying the effect of weight loss through calorie restricted diet on apoptotic factor levels of cytokeratin 18 and indicators of liver dysfunction in patients with non-alcoholic steatohepatitis (NASH)

Public title

Effect of weight loss on improvement of liver inflammation and fibrosis in non- alcoholic fatty liver patients through calorie restricted diet

Purpose

Treatment

Inclusion/Exclusion criteria
 Inclusion criteria: 1. BMI 25-40: Hepatic fibrosis 2 and higher: Liver enzymes 1.5 times more natural Exclusion criteria: Viral hepatitis B, c : Liver Cancer: alcohol consumption: Pregnancy : Hepatic autoimmune diseases: Taking hepatotoxic drugs: Taking vitamin D supplement pills : Patient's denial: Failure to observe the diet

Age
 From **18 years** old to **70 years** old

Gender
 Both

Phase
 N/A

Groups that have been masked
No information

Sample size
 Target sample size: **60**

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

The Ethics Committee of Mashhad University of Medical Sciences

Street address

Nutrition group. Medicine faculty. Mashhad university of medical sciences. vakilabad blvd. azadi sqr. Mashhad

City

Mashhad

Postal code

9177948564

Approval date

2017-08-09, 1396/05/18

Ethics committee reference number

IR.MUMS.fm.REC.1395.498

Health conditions studied

1

Description of health condition studied

Non-Alcoholic Fatty Liver - Non -Alcoholic Steatohepatitis

ICD-10 code

K75.8

ICD-10 code description

Other specified inflammatory liver diseases

Primary outcomes

1

Description

Cytokeratin 18

Timepoint

First, 3 and 6 months after intervention

Method of measurement

ELIZA Kit

2

Description

Liver dysfunction factors

Timepoint

First.3 and 6 months after intervention

Method of measurement

Biochemistry Lab

Secondary outcomes

1

Description

Liver Fibrosis

Timepoint

First,6 months after intervention

Method of measurement

Fibroscan Of liver

2

Description

Anthropometric measurements

Timepoint

first, 3 and 6 months after the intervention

Method of measurement

BIA device. Measuring body size with meter

Intervention groups

1

Description

This study includes a group of 60 patients with non-alcoholic fatty liver disease. Intervention is performed for all of these patients and the study does not have the control group. The intervention includes a restricted calorie diet of 500 kcal for people with a BMI of 25-30 and a 1000 kcal for people with a BMI of 30-40.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Fiber scan center , Apadana Diagnostic Clinic.

Full name of responsible person

Dr.azita ganji

Street address

Apadana building ,East Golestan St. , Mashhad

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Mashhad University of Medical Sciences

Full name of responsible person

Mohammad Safarian

Street address

Nutrition group. Medicine faculty. Mashhad university of Medical Sciences. vakilabad blvd. azadi sqr. Mashhad

City

Mashhad

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 of Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Dr.Mohammad Safarian

Position

Nutritionist ,Associate Professor of nutrition group ,Mashhad University of Medical Sciences

Other areas of specialty/work

Street address

Nutrition group. Medicine faculty. Mashhad university of Medical Sciences. vakilabad blvd. azadi sqr.

Mashhad

City

Mashhad

Postal code

9177948564

Phone

+51 38828888051

Fax

+98 38828560

Email

med.faculty[AT]mums.ac.irsafarianm@mums.ac.irmo
hammadps941@mums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad university of medical sciences

Full name of responsible person

Dr. Mohammad Safarian

Position

Nutritionist ,Associate Professor of nutrition group ,Mashhad University of Medical sciences

Other areas of specialty/work

Street address

Nutrition group. Medicine faculty. Mashhad university of medical sciences. vakilabad blvd. azadi sqr. Mashhad

City

Mashhad

Postal code

Phone

+98 51 3882 8888

Fax

Email

med.faculty[AT]mums.ac.irsafarianm@mums.ac.irmo
hammadps941@mums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Nutrition group. Medicine faculty. Mashhad university of Medical Sciences

Full name of responsible person

Sepideh Mohammadpour

Position

MSC Nutrition Student ,Mashhad university of Medical Sciences

Other areas of specialty/work

Street address

Nutrition group. Medicine faculty. Mashhad university of Medical Sciences. vakilabad blvd. azadi sqr. Mashhad

City

Mashhad

Postal code

Phone

00

Fax
Email mohammadps941@mums.ac.ir
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