Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Nov 2026

Clinical trial for evaluation of Kashoos herbal syrup on clinical and paraclinical symptoms (enzymes and liver sonography) of patients of 25 to 50 years old with Non-Alcoholic Steatohepatitis (NASH)

Protocol summary

Summary

The purpose of this research is to evaluate of Kashoos herbal syrup on clinical and paraclinical symptoms of patients affected of fatty liver. The patients with 25 to 50 years old in Liver Clinic of the Firoozgar Hospital who were not affected of other agents of chronic hepatitis including chronic active viral hepatitis, liver metabolic disorders, autoimmune, drug side effects and negative alcohol consumption with positive fatty liver markers (LFT-sonography) for 6 months before study are invited. After giving explanations about the disease and treatment regardless of patients' written consent will be obtained and then the patients enrolled in the study. Initially patients received recommendations in terms of changing lifestyle, physical activity and followed up for three months. If continuous high level of liver enzymes observe in patients, they will enter the second phase. For all patients, a questionnaire including demographic (gender and age), anthropometric (height, weight and BMI), clinical symptoms, bowel symptoms and test results of laboratory and sonography of the liver is completed. With confirmed existence of active fatty liver (high liver enzymes and evidence of sonography), patients are treating with Kashoos syrup for 3 months, ten ml, three meals daily, half an hour before the main meal food. Patients are visited monthly for weight indexes, abdominal circumference (at three points around the navel, above and below the navel), blood pressure (in three positions of lying, sitting and standing) and gastrointestinal, nervous and other symptoms in patients with liver enzymes are measured and recorded. Sonography will be assessed after treatment. Process of response to treatment will follow with sonography (before and after the intervention), clinical and laboratorial parameters (monthly). In the absence of regular follow-up treatment in 2 consecutive visits, volunteers are excluded and a new volunteer enters. With the completion of the 40 persons the study will complete and the data will be presented to one other than those involved in the clinical study for analyze.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014120320197N1**
Registration date: **2015-12-14, 1394/09/23**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-12-14, 1394/09/23

Registrant information

Name
monirsadat roohollahi
Name of organization / entity
Mashhad University
Country
Iran (Islamic Republic of)
Phone
+98 21 7720 3531
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roohollahi@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2015-08-23, 1394/06/01

Expected recruitment end date

2015-12-22, 1394/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial for evaluation of Kashoos herbal syrup on clinical and paraclinical symptoms (enzymes and liver sonography) of patients of 25 to 50 years old with Non-Alcoholic Steatohepatitis (NASH)

Public title

Evaluation of Kashoos syrup on clinical and paraclinical symptoms of patients with Non-Alcoholic Steatohepatitis (NASH)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: non presence of CAH; hepatotoxic drug; alcoholic drinks; uncontrolled hypothyroidism; elevation of LFT 6 months before exam; presence of fatty liver in sonography; non using herbal or chemical drugs effective on fatty liver. Exclusion criteria: absence in 2 consecutive visits; demonstration of any unexpected medical side effects (refereed to Liver Clinic of Traditional Medicine).

Age

From **25 years** old to **50 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)

Single blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Since this intervention by kashoos syrup in the treatment of fatty liver was the first clinical trial and no similar work has been done yet, the study has been done as a pilot study and a formula to determine the sample size was not used.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran University

Street address

Quods avenue

City

Tehran

Postal code

Approval date

2015-08-08, 1394/05/17

Ethics committee reference number

IR.TUMS.REC.1394.534

Health conditions studied

1

Description of health condition studied

Nonalcoholic steatohepatitis (NASH)

ICD-10 code

K75.8

ICD-10 code description

One of specified inflammatory liver diseases

Primary outcomes

1

Description

Liver enzymes (ALT, AST)

Timepoint

Monthly

Method of measurement

Laboratory

2

Description

Degree of fatty liver in sonography

Timepoint

Before and after intervention

Method of measurement

Ultrasound

3

Description

Abdominal circumference at three points (around the navel, above and below the navel)

Timepoint

Monthly

Method of measurement

Meter

4

Description

Blood pressure in three positions (lying, sitting and standing)

Timepoint

Monthly

Method of measurement
Mercury sphygmomanometer

Secondary outcomes

empty

Intervention groups

1

Description
Consumption of ten ml of Kashoos herbal syrup three meals daily, half an hour before the main meal food with half cup of boiling water for 3 months
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Liver Clinic of Firoozgar Hospital
Full name of responsible person
Monirosadat Roohollahi
Street address
Behafarin avenue, Valiasr square
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Traditional Medicine College of Mashhad University of Medical Sciences
Full name of responsible person
Dr. Monirosadat Roohollahi
Street address
East Razi avenue, Tenth of Day square
City
Mashhad
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Traditional Medicine College 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
Traditional Medicine College of Mashhad University of Medical Sciences
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Person responsible for updating data

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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