

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 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

###### Email address

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

#### Full name of responsible person

Dr. monirosadat Roohollahi

#### Position

PHD student of traditional medicine

#### Other areas of specialty/work

#### Street address

No 36, Bagheri alley, Hengam avenue, Resalat square.

#### City

Tehran

#### Postal code

#### Phone

+98 21 7720 3531

#### Fax

#### Email

roohollahi@razi.tums.ac.ir; asadi.mj@gmail.com

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Traditional Medicine College of Mashhad University of Medical Sciences

#### Full name of responsible person

Dr. Monirosadat Roohollahi

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## Person responsible for updating data

### Contact

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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*