# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Nov 2026

## Study of phlebotomy efficacy in improvement of liver fibrosis and its function among patients with non alcoholic steatohepatitis

### Protocol summary

**Study aim**
Impact of phlebotomy on steatohepatitis

**Design**
In this research, 40 eligible patients with non-alcoholic fatty liver disease referring to Qom gastroenterology clinic were chosen purposefully. Then, patients by block randomization were randomly divided into two control and intervention groups.

**Settings and conduct**
The study was performed as a randomized clinical trial at Shahid Beheshti Hospital in Qom. The study is single-blinded, and intervention is conducted by someone other than the care provider, and care provider is unaware of the type of treatment.

**Participants/Inclusion and exclusion criteria**
patient was included in this study that, aged 18 to 65 years old and they are not anemic and by laboratory tests and fibroscan, non-alcoholic fatty liver disease has been proven in them. Patients with underlying illness will also be excluded from the study.

**Intervention groups**
For the intervention group after fibroscan and diagnosis of the disease in the first and fifth months, phlebotomy (with a needle and a blood transfusion bag of 400 cc each time from the median cubital vein) and for the second group where the control group performed phlebotomy not to be. Both groups are advised to improve lifestyle (proper diet and exercise) and prescribe vitamin E

**Main outcome variables**
At the end of the sixth month, fibroscan and lab tests were performed for both groups for evaluation of fatty liver severity.

### General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20161205031252N4**
Registration date: **2017-12-06, 1396/09/15**
Registration timing: **registered_while_recruiting**

Last update: **2017-12-06, 1396/09/15**
Update count: **0**

**Registration date**
2017-12-06, 1396/09/15

**Registrant information**

**Name**
Ahmad Hormati

**Name of organization / entity**
Qom university of Medical Sciences

**Country**
Iran (Islamic Republic of)

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+98 25 3612 2053

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**Recruitment status**
**Recruitment complete**

**Funding source**
medical university of qom

**Expected recruitment start date**
2017-07-27, 1396/05/05

**Expected recruitment end date**
2018-01-20, 1396/10/30

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
Study of phlebotomy efficacy in improvement of liver fibrosis and its function among patients with non alcoholic steatohepatitis

**Public title**
Impact of phlebotomy on steatohepatitis
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
age between 18-65 years proven steatohepatitis with sonography or fibro scan Hb more than 13 in men and more than 12 in women Informed consent
**Exclusion criteria:**
any other liver disease history of alcohol use (more than 10gr daily for women and more than 20gr daily for men) pregnant and lactating women women in childbearing age with no reliable Contraception method weight under 50kg uncontrolled underlying disease contraindication of vitamin E use
**Age**
From **18 years** old to **65 years** old
**Gender**
Both

**Phase**
N/A
**Groups that have been masked**

- Care provider

**Sample size**
Target sample size: **40**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
block randomization, Unit of randomization:individual
**Blinding (investigator's opinion)**
Single blinded
**Blinding description**
Care provider is blinded
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics Committee of Qom University of Medical Sciences
**Street address**
No. 83, 4th alley, 1.1 alley, Safashahr Blvd
**City**
Qom
**Province**
Ghoum
**Postal code**
3716987366
**Approval date**
2017-05-23, 1396/03/02
**Ethics committee reference number**
IR.MUQ.REC.1396.29

## Health conditions studied

### 1

**Description of health condition studied**
Nonalcoholic steatohepatitis (NASH)
**ICD-10 code**
K75.8
**ICD-10 code description**
Other specified inflammatory liver diseases

## Primary outcomes

### 1

**Description**
liver fibrosis
**Timepoint**
before intervention and after 6 month
**Method of measurement**
fibroscan

### 2

**Description**
liver function
**Timepoint**
before intervention and after 6 month
**Method of measurement**
Blood samples laboratory study

## Secondary outcomes

### 1

**Description**
ferritin level
**Timepoint**
at the begining of study and 6 months later
**Method of measurement**
Laboratory blood level measurement

## Intervention groups

### 1

**Description**
Intervention group: Phlebotomy at first and fifth months, (with a needle and a blood transfusion bag, 400 cc each time from the median cubital vein) with routine treatment
**Category**
Treatment - Other

**2**

**Description**
Control group: Routine treatment
**Category**
N/A

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Shahid Beheshti Hosbital
**Full name of responsible person**
Ahmad Hormati
**Street address**
Shahid Beheshti Hospital, Shahid Beheshti Blvd, Azadegan Square.
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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Ghoum University of Medical Sciences
**Full name of responsible person**
Hossein Saghafi
**Street address**
Gastroenterology and Hepatology Disease Research Center, Shahid Beheshti Hospital, Shahid Beheshti Blvd, Azadegan Squ
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**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Ghoum University of Medical Sciences
**Proportion provided by this source**
100
**Public or private sector**
Public
**Domestic or foreign origin**
Domestic
**Category of foreign source of funding**
*empty*
**Country of origin**
**Type of organization providing the funding**
Academic

## Person responsible for general inquiries

**Contact**
**Name of organization / entity**
Ghoum University of Medical Sciences
**Full name of responsible person**
Ahmad Hormati
**Position**
Assistant Professor
**Latest degree**
Subspecialist
**Other areas of specialty/work**
Internal Medicine
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
No - There is not a plan to make this available
**Justification/reason for indecision/not sharing IPD**
The data are specific to this study
**Study Protocol**
No - There is not a plan to make this available
**Statistical Analysis Plan**
No - There is not a plan to make this available
**Informed Consent Form**
No - There is not a plan to make this available
**Clinical Study Report**
No - There is not a plan to make this available
**Analytic Code**
No - There is not a plan to make this available
**Data Dictionary**
No - There is not a plan to make this available