Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Jun 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

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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
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Sponsors / Funding sources

1

Sponsor
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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
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Assistant Professor
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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