Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jul 2026

Investigation of the effects of wet cupping therapy on some inflammatory factors in patients affected by non-alcoholic fatty liver disease (NAFLD)

Protocol summary

Study aim
Assessing the effects of wet cupping therapy on some inflammatory cytokines pre- and post-treatment such as hs-CRP\ IL-6 \ IL-1β \ TNF-α Assessing the hemological and biochemical modifications pre- and post-treatment on lipid profile and liver enzymes

Design
A quasi-experimental trial study with self-controls on 20 patients

Settings and conduct
This quasi-experimental trial study with self-controls is conducted on 20 study subjects selected in Omid Clinic in Hamadan- Iran according to our criteria inclusion through medical examinations by our experts in Iranian Medicine

Participants/Inclusion and exclusion criteria
Men and women from 20- to 60-year-old affected by non alcoholic fatty liver disease grade II and III proved by ultrasonography of the liver, with or without alteration in their liver enzymes are included in the study. Patients who were affected by other chronic liver diseases or hepatitis and anemia; also heavy smokers, alcohol drinkers and patients with prolonged intake of drugs induced fatty liver diseases are excluded from the study.

Intervention groups
Wet cupping therapy every 15 days for a total of three times on all patients

Main outcome variables
Modifications on inflammatory cytokines such as hs-CRP / IL-1β / IL-6 / TNF-α

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220425054654N1**
Registration date: **2022-07-07, 1401/04/16**
Registration timing: **retrospective**
Last update: **2022-07-07, 1401/04/16**
Update count: **0**

Registration date
2022-07-07, 1401/04/16

Registrant information

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Nooshin Abbasi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-04-03, 1400/01/14

Expected recruitment end date
2021-08-05, 1400/05/14

Actual recruitment start date
2021-07-06, 1400/04/15

Actual recruitment end date
2021-11-13, 1400/08/22

Trial completion date
2021-12-18, 1400/09/27

Scientific title
Investigation of the effects of wet cupping therapy on some inflammatory factors in patients affected by non-alcoholic fatty liver disease (NAFLD)

Public title
Effects of wet cupping therapy in non-alcoholic fatty liver disease

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Men and women affected by non alcoholic fatty liver disease grade II and III proved by ultrasonography of the liver NAFLD patients with or without alteration in their liver enzymes
Exclusion criteria:
Patients who were affected by other chronic liver diseases or hepatitis and anemia Heavy smokers Alcohol drinkers with intake greater than 2 alcohol units (20 g/day) for women and greater than three alcohol units (30 g/day) for men Patients with prolonged intake of drugs induced fatty liver diseases such as amiodarone, perhexiline, DH, steroid hormones, tamoxifen and ...

Age
From **20 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **20**
Actual sample size reached: **16**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features
A quasi-experimental trial study with self-controls

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of the Faculty of Medicine, Hamadan University of Medical Sciences
Street address
Fahmideh St. Research center for molecular medicine, Hamadan University of Medical Sciences, Hamadan, Iran
City
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Province
Hamadan
Postal code
6517838736
Approval date
2021-07-03, 1400/04/12
Ethics committee reference number
IR.UMSHA.REC.1400.291

Health conditions studied

1

Description of health condition studied
Non-alcoholic fatty liver disease (NAFLD)
ICD-10 code
K76.0
ICD-10 code description
Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description
Modification on inflammatory cytokine Tumor Necrosis Factor-α (TNF-α)
Timepoint
Measuring the level of inflammatory cytokine Tumor Necrosis Factor-α (TNF-α) at the beginning of the study (before intervention) and after 48 hours of each wet cupping. Wet cupping therapy was applied once every 15 days for a total of three times
Method of measurement
Enzyme-linked immunosorbent quantitative assay (ELISA) kit is used to measure the modification level of inflammatory cytokine Tumor Necrosis Factor-α (TNF-α).

2

Description
Modification on inflammatory cytokine Interleukin-1β (IL-1β)
Timepoint
Measuring the level of inflammatory cytokine Interleukin-1β (IL-1β) at the beginning of the study (before intervention) and after 48 hours of each wet cupping. Wet cupping therapy was applied once every 15 days for a total of three times
Method of measurement
Enzyme-linked immunosorbent quantitative assay (ELISA) kit is used to measure the modification level of inflammatory cytokine Interleukin-1β (IL-1β).

3

Description
Modification on inflammatory cytokine Interleukin-6 (IL-6)
Timepoint
Measuring the level of inflammatory cytokineInterleukin-6 (IL-6) at the beginning of the study (before intervention) and after 48 hours of each wet cupping. Wet cupping therapy was applied once every 15 days for a total of three times
Method of measurement
Enzyme-linked immunosorbent quantitative assay (ELISA) kit is used to measure the modification level of inflammatory cytokine Interleukin-6 (IL-6).

4

Description
Modification on High sensitivity C-reactive protein (hs-CRP) level

Timepoint
Measuring the level of High sensitivity C-reactive protein (hs-CRP) at the beginning of the study (before intervention) and after 48 hours of the last wet cupping (third wet cupping). Wet cupping therapy was applied once every 15 days for a total of three times

Method of measurement
High sensitivity C-reactive protein was measured by CRP detection kit (Nephelometry)

Secondary outcomes

1

Description
serum lipids' level

Timepoint
Measuring the level of reduction on serum lipid profile at the beginning of the study (before intervention) and after 48 hours of last wet cupping. Wet cupping therapy was applied once every 15 days for a total of three times

Method of measurement
The reduction of serum lipid profile low-density lipoprotein- cholesterol (LDL-C) and high-density lipoprotein- cholesterol was measured by quantitative kit.

2

Description
liver enzymes' level

Timepoint
Measuring the level of reduction on modifying liver enzymes' profile at the beginning of the study (before intervention) and after 48 hours of last wet cupping. Wet cupping therapy was applied once every 15 days for a total of three times

Method of measurement
The modification of liver enzymes' profile alanine transaminase (ALT) and aspartate aminotransferase (AST) was measured by activity assay kit.

Intervention groups

1

Description
Intervention group: wet cupping therapy was done on all patients in an only group, which was our control group, once every 15 days for a total of three times. Patients sit cross-legged on the bed. The intrascapular area, brown adipose tissue, was disinfected and suctioned through negative pressure created by a vacuumed cup connected to a suction device. Then the skin under the cup area was scarified with multiple superficial oblique scratches, and blood flown into the cup following the second suction. The cup was removed and the extracted blood was gently cleaned from the skin surface. The suction and extracting capillary blood were repeated three times on the same site. Finally, the location of cupping was cleaned and covered by a layer of honey and a sterile gauze was fixed on it with surgical tapes.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Research center for molecular medicine, Hamadan University of Medical Sciences

Full name of responsible person
Rezvan Najafi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran's National Elites Foundation (INEF)

Full name of responsible person
Meisam Noori

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No.209 Azadi St., between Navvab St. and Roodaki St., at the corner of Tahernia lane, Tehran

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Grant name
Iran's National Elites Foundation (INEF). Iranian cooperation postdoctoral program for oversees specialists

Grant code / Reference number
11/61788

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Iran's National Elites Foundation (INEF)

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
Hamedan University of Medical Sciences

Full name of responsible person
Rezvan Najafi

Position
Assistant professor

Latest degree
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable