Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jul 2026

The effects of caffeine supplementation on clinical parameters and disease severity in patients with hepatic cirrhosis

Protocol summary

Study aim
Determining the effects of caffeine supplementation on clinical indicators and disease severity in cirrhotic patients

Design
A randomized, double-blinded, controlled clinical trial with a parallel-group design of 42 patients. Random number table will be used for randomization.

Settings and conduct
50 eligible patients with cirrhosis will randomly take two capsules daily, each containing 200 mg of caffeine or placebo for 8 weeks. All patients will also receive standard medical treatment. 12 cc blood samples will be taken from all patients before and after the intervention, to determine CBC, kidney and liver function, and inflammatory markers and patients' clinical signs will be recorded during the study. None of the participants will be aware of the type of capsule received. In this study participants and investigators will be blinded and concealment will be done by a third person

Participants/Inclusion and exclusion criteria
Individuals who are willing to cooperate in the research and with a clinical diagnosis of liver cirrhosis who refer to Taleghani Hospital, if they are in the age range of 18 to 75 years and have the ability to receive the capsules orally, will be included in the study. Also, people who are pregnant or breastfeeding, have a history of caffeine allergy, consume more than 3 cups of coffee a day, and those with extrahepatic insufficiency will not be included in the study.

Intervention groups
1- Caffeine group: receiving 400mg of caffeine daily in the form of 200mg tablet for 8 weeks 2-Placebo group: placebo tablets containing starch for 8 weeks

Main outcome variables
Blood platelet levels, Model for end-stage liver cirrhosis (MELD) score, child-pugh score and fibrosis 4 score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20100524004010N34**
Registration date: **2022-07-08, 1401/04/17**
Registration timing: **registered_while_recruiting**

Last update: **2022-07-08, 1401/04/17**
Update count: **0**

Registration date
2022-07-08, 1401/04/17

Registrant information

Name
Azita Hekmatdoost

Name of organization / entity
Shahid Beheshti University of Medical Sciences, National Institute of Nutrition Research

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-07-03, 1401/04/12

Expected recruitment end date
2022-10-04, 1401/07/12

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effects of caffeine supplementation on clinical parameters and disease severity in patients with hepatic cirrhosis

Public title
The effects of caffeine supplementation on clinical parameters and disease severity in patients with hepatic cirrhosis

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Having desire to participate in the study Age range of 18-75 BMI between 18.5 to 30 kg per square meter Do not develop extrahepatic organ failure Do not take caffeinated drugs for one month before the start of the study Do not consume more than 3 cups of coffee per day Not pregnant or breastfeeding

Exclusion criteria:
The patient's unwillingness to continue cooperation Patients who have consumed less than 80% of the capsules. The diagnosis of the treating physician at the end of the patient's participation in the study Pregnancy or breastfeeding Loss of more than 10% of body weight during the study period

Age
From **18 years** old to **75 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **25**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, participants were classified into two groups with normal (18.5-24.9) and overweight (24.9-29.9) by stratified blocked randomization method and based on BMI and randomly assigned to One of the groups caffeine consumption or placebo consumption group. Separate randomization is done based on BMI within each group. The size of the blocks is 4, with two assignments to the intervention group (A) and two allocations to the control group (B). There are 6 different permutations of AABB, ABAB, BBAA, BABA, ABBA, BAAB.

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients won’t know if they are receiving the caffeine or a placebo for double-blinding the study, the bottles containing the relevant soft gels will be concealed as A and B by a third person at the beginning of the study, and none of the research team members will know the type of soft gels received by each group.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of the National Institute of Nutritional Research and Food Industry

Street address
No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town

City
Tehrab

Province
Tehran

Postal code
1981619573

Approval date
2022-05-24, 1401/03/03

Ethics committee reference number
IR.SBMU.NNFTRI.REC.1401.009

Health conditions studied

1

Description of health condition studied
Hepatic Cirrhosis

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Model for end-stage liver cirrhosis score (MELD score)

Timepoint
At the beginning and the end of the study

Method of measurement
Using the formula

Secondary outcomes

1

Description
Serum total billirubin

Timepoint
At the beginning and the end of the study

Method of measurement
Enzymatic method

2

Description
Serum albumin
Timepoint
At the beginning and the end of the study
Method of measurement
Enzymatic method

3

Description
Serum Alanine transaminase (ALT)
Timepoint
At the beginning and the end of the study
Method of measurement
Enzymatic method

4

Description
Serum Aspartate aminotransferase (AST)
Timepoint
At the beginning and the end of the study
Method of measurement
Enzymatic method

5

Description
Serum creatinine
Timepoint
At the beginning and the end of the study
Method of measurement
Enzymatic method

6

Description
Serum Na
Timepoint
At the beginning and the end of the study
Method of measurement
Enzymatic method

7

Description
Serum Alkaline phosphate (ALP)
Timepoint
At the beginning and the end of the study
Method of measurement
Enzymatic method

8

Description
International normalized ratio (INR)
Timepoint
At the beginning and the end of the study
Method of measurement
Calculate the ratio

9

Description
Prothrombin time (PT)
Timepoint
At the beginning and the end of the study
Method of measurement
Prothrombin time measurement

10

Description
Partial thromboplastin time (PTT)
Timepoint
At the beginning and the end of the study
Method of measurement
Partial Thromboplastin Time measurement

11

Description
Serum platelets
Timepoint
At the beginning and the end of the study
Method of measurement
Automatic cell count

12

Description
Tumor necrosis factor-alpha (TNF-a)
Timepoint
At the beginning and the end of the study
Method of measurement
ELISA method

13

Description
Interleukin 6 (IL-6)
Timepoint
At the beginning and the end of the study
Method of measurement
ELISA method

14

Description
Serum c-reactive protein (CRP)
Timepoint
At the beginning and the end of the study
Method of measurement
ELISA method

15

Description
Child pugh score
Timepoint
At the beginning and the end of the study
Method of measurement
Using the formula

16

Description
Fibrosis 4 score
Timepoint
At the beginning and the end of the study
Method of measurement
Using the formula

17

Description
AST to platelets ratio index (APRI)
Timepoint
At the beginning and the end of the study
Method of measurement
Calculate the ratio

Intervention groups

1

Description
Intervention group: Will take 400 mg of caffeine daily in the form of two tablets each contains 200 mg of caffeine (Product of raha Company) orally for eight weeks.
Category
Other

2

Description
Control group: Will take two placebo tablets daily, which are similar in shape and taste to caffeine tablets, orally for eight weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Taleghani General Hospital
Full name of responsible person
Behzad Hatami
Street address
Ayatollah Taleghani Educational Hospital, Araabi St., Yaman Ave, Chamran High Way, Tehran, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr. Seyed Ali Ziayi
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Medical School- next to Taleghani Hospital- Evin- Shahid Chamran Highway
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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Azita Hekmatdoost
Position
Professor
Latest degree
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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
Undecided - It is not yet known if there will be a plan to make this available

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

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

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

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