Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Assessing the synergistic effect of milk thistle extract, curcumin, n-acetylcystein, artichoke extract, vitamin D, and Chromium compared to placebo on liver function in patients with non-alcoholic fatty liver (NAFLD)

Protocol summary

Study aim
Determinig the synergistic effects of milk thistle extract, curcumin, n-acetylcystein, artichoke extract, vitamin D and Chromium picolinate compared to placebo on liver function in patients with non-alcoholic fatty liver (NAFLD)

Design
66 participants (no=33 per group) are randomly assigned to intervention and placebo group using random digit table

Settings and conduct
This double blinded study will be performed in Fayaz Bakhsh Hospital. At base line and after 12 weeks of intervention with supplement/placebo, liver function tests (ALT, AST, ALK-Ph) , Fibrosis-4 (FIB-4), AST to Platelet Ratio Index (APRI) score and lipid profile (T.Chol, LDL-c, HDL-c, TG) will be recorded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Liver function enzymes higher than normal level, Fatty liver diagnosis based on sonography, Age>18 years Willing to participate in the study
Exclusion criteria: having known kidney disease, having known heart disease, pregnancy or lactation

Intervention groups
Patients will receive 1000 mg supplement capsule or placebo once daily for 12 weeks. Each capsule contains 175 mg milk thistle extract, 250 mg curcumin, 150 mg n-acetylcystein, 250 mg artichoke extract, 600 IU vitamin D, 100 mcg Chromium picolinate and 100 mg crumium picolinate and maltodextrine in placebo group.

Main outcome variables
Liver function tests (ALT, AST, ALK-Ph), Fibrosis-4 (FIB-4), AST to Platelet Ratio Index (APRI)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20140804018677N27**
Registration date: **2023-08-19, 1402/05/28**
Registration timing: **prospective**

Last update: **2023-08-19, 1402/05/28**
Update count: **0**

Registration date
2023-08-19, 1402/05/28

Registrant information

Name
soodeh razeghi Jahromi

Name of organization / entity
Tehran University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-09-06, 1402/06/15

Expected recruitment end date
2024-03-05, 1402/12/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Assessing the synergistic effect of milk thistle extract, curcumin, n-acetylcystein, artichoke extract, vitamin D, and Chromium compared to placebo on liver function in patients with non-alcoholic fatty liver (NAFLD)

Public title
effect of milk thistle extract, curcumin, n-acetylcystein, artichoke extract, vitamin D, and Chromium on non-alcoholic fatty liver
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Fatty liver diagnosis based on sonography Age>18 years Willing to participate in the study
Exclusion criteria:
Having known kidney disease Having known heart disease Pregnancy or lactation
Age
From **18 days** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **33**
Randomization (investigator's opinion)
Randomized
Randomization description
Block Randomization method is used to randomize the patients. For randomization, we will visit the www.sealedenvelope.com and use randomization tab to make a list considering the number of intervention groups, sample size, block size (4 is selected for current study). The prepared list that contains the pattern of patient allocation will be obtained and used. This site is designed in such a way that there is no limit on the number of groups for random allocation. According to the total number of samples required for the study, which is 80 patients (40 patients in the intervention group (A) and 40 patients in the control group (B)), 20 blocks with a volume of four includes two groups A and B will be randomly selected using the software, such as (ABAB) ، (BBAB)، (AABB)، (ABBA)، (BAAB .....(Then 80pockets (40 pockets containing paper containing A and 40 pockets containing B) will be prepared based on sample size. According to a list of blocks, a trained person outside of the research team will be set the row of pockets. After admission of each patient will be given a pocket and assigned to Group A (intervention) or B (control group), and the sample process will be performed sequentially until the end of completion of sample size.
Blinding (investigator's opinion)
Double blinded
Blinding description
It is a double blind study. A third person out of study team (clinic secretary) have the sequence of codes that provide the team with sealed pockets coded as A or B at the time of sampling. The following groups of people involved in the trial: participants, research team including principle investigator, data collectors, and outcome assessors will be blind. After analyzing the data investigators and outcome assessors will be unblinded about A and B group allocation to supplement and placebo. Patients in supplement and placebo groups will receive packages of similar capsules.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of National Nutrition and Food Technology Reseach Institute
Street address
No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town
City
Tehran
Province
Tehran
Postal code
1981619573
Approval date
2023-06-13, 1402/03/23
Ethics committee reference number
IR.SBMU.NNFTRI.REC.1402.017

Health conditions studied

1

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

Primary outcomes

1

Description
Alanine Aminotransferase (ALT) enzyme
Timepoint

Baseline and at the end of the study
Method of measurement
Biochemical kit

2

Description
Aspartate transaminase (AST) enzyme
Timepoint
Baseline and at the end of the study
Method of measurement
Biochemical kit

3

Description
Fibrosis-4 (FIB-4)
Timepoint
Baseline and at the end of the study
Method of measurement
Biochemical kit

4

Description
AST to Platelet Ratio Index (APRI)
Timepoint
Baseline and at the end of the study
Method of measurement
Calculation based on biochemical kit

5

Description
Alkaline phosphatase (Alk-ph) enzyme
Timepoint
Baseline and at the end of the study
Method of measurement
Biochemical kit

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Supplement (1000 mg), Samanic company, daily for12 weeks
Category
Treatment - Other

2

Description
Control group: Placebo contain maltodextrine, (1000 mg), Samanic company, daily for12 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Fayaz Bakhsh Hospital
Full name of responsible person
Soodeh Razeghi Jahromi
Street address
No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town,
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Samanik Salamat Gostar Company
Full name of responsible person
Shamsali Rezazadeh
Street address
No 506-2, Naderi St, Keshavarz Blvd.
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1416613485
Phone
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Email
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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
Samanik Salamat Gostar Company
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Soodeh Razghei Jahromi

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Not applicable

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is 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

Title and more details about the data/document
Coded data of the participants, study protocol, and report of the main output of the study would be available in case of researchers' reasonable request sending to principal investigator of the study 6 months after publishing the article.

When the data will become available and for how long
starting 6 months after publication

To whom data/document is available
University researchers

Under which criteria data/document could be used
Have no other condition

From where data/document is obtainable
Email to soodehrazeghi@gmail.com

What processes are involved for a request to access data/document
sending email

Comments