Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jun 2026

The effect of jujube on anthropometric , biochemical and hepatic steatosis predictors indices in patients with non-alcoholic fatty liver disease

Protocol summary

Study aim

Determining the effect of jujube on anthropometric, biochemical and hepatic steatosis predictors indices in patients with non alcoholic fatty liver disease

Design

The current study is a phase 3 single-blind controlled clinical trial with two parallel groups (intervention and control). Forty-four eligible patients will be randomly assigned to each group (88 participants in total)

Settings and conduct

Eighty eight eligible patients who referred to Hazrat Abolfazl Hospital in Kermanshah are randomly assigned to 2 study groups. Intervention group will receive 30 gr jujube powder along with a low-calorie diet(500 Kcal reduction) for12 weeks. Control group will receive a low-calorie diet(500 Kcal reduction) for12 weeks. Anthropometrics indices, biochemical and hepatic steatosis predictors indices, will be assessed before and after the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diagnosed patients with nonalcoholic fatty liver, not abusing alcohol, not having diabetes, kidney disorders and other liver diseases, Not having liver cancer, or other cancers, not having allergy to Jujube and not taking multivitamins and minerals supplements in 3 month ago. Exclusion criteria:Pregnancy .

Intervention groups

The intervention group will consume 30 grams of jujube powder (Shaina Sharq Jujube company) daily, for 12 weeks. All the patients (intervention and control groups)will be given a low-calorie diet (500 Kcal reduction).

Main outcome variables

FBS

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140502017522N5**
Registration date: **2023-06-07, 1402/03/17**
Registration timing: **prospective**

Last update: **2023-06-07, 1402/03/17**
Update count: **0**

Registration date

2023-06-07, 1402/03/17

Registrant information

Name

Maryam Taghdir

Name of organization / entity

Baqiyatallah University of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8755 5511

Email address

mtaghdir@bmsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-22, 1402/04/01

Expected recruitment end date

2024-01-19, 1402/10/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of jujube on anthropometric , biochemical and hepatic steatosis predictors indices in patients with non-alcoholic fatty liver disease

Public title
The effect of jujube in management patients with non-alcoholic fatty liver

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
diagnosed patients with nonalcoholic fatty liver not abusing alcohol not having diabetes, kidney disorders and other liver diseases Not having liver cancer, or other cancers not having allergy to Jujube not taking multivitamins and minerals supplements during 3 month ago

Exclusion criteria:
pregnancy

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **88**

Randomization (investigator's opinion)
Randomized

Randomization description
Random allocation will be done using the block randomization method (block size= four). The possible blocks will be as follows:1- AABB, 2- ABAB، 3- BABA ، 4- BBAA، 5- BAAB، 6- ABBA Then, numbers (1 to 6) will be randomly selected using the random number table, and this process will be repeated 22 times until the sample size is reached.

Blinding (investigator's opinion)
Single blinded

Blinding description
Outcome assessor and data analyser will be blinded.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Commmittee of Baqiyatallah Hospital

Street address
Baqiyatallah university, south sheikh bahai st, molasdra st, vanak sq

City
Tehran

Province
Tehran

Postal code
1435916471

Approval date
2023-04-29, 1402/02/09

Ethics committee reference number
IR.BMSU.BAQ.REC.1402.010

Health conditions studied

1

Description of health condition studied
Non alcoholic fatty liver disease

ICD-10 code
K76.0

ICD-10 code description
Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description
Fasting blood sugar (FBS)

Timepoint
At the beginning of the study and after the intervention (12 weeks after the start of the intervention)

Method of measurement
Standard enzymatic method

Secondary outcomes

1

Description
Weight

Timepoint
At the beginning of the study and after the intervention (12 weeks after the start of the intervention)

Method of measurement
scale

2

Description
Waist circumference

Timepoint
At the beginning of the study and after the intervention (12 weeks after the start of the intervention)

Method of measurement

tape measure

3

Description
Body mass index
Timepoint
At the beginning of the study and after the intervention (12 weeks after the start of the intervention)
Method of measurement
Standard formula

4

Description
Aspartate aminotransferase (AST)
Timepoint
At the beginning of the study and after the intervention (12 weeks after the start of the intervention)
Method of measurement
Enzyme-linked immuno_sorbent assay (ELISA)

5

Description
Total cholesterol
Timepoint
At the beginning of the study and after the intervention (12 weeks after the start of the intervention)
Method of measurement
Standard enzymatic method

6

Description
high density lipoprotein
Timepoint
At the beginning of the study and after the intervention (12 weeks after the start of the intervention)
Method of measurement
Standard enzymatic method

7

Description
low density lipoprotein
Timepoint
At the beginning of the study and after the intervention (12 weeks after the start of the intervention)
Method of measurement
Standard enzymatic method

8

Description
triglyceride
Timepoint
At the beginning of the study and after the intervention (12 weeks after the start of the intervention)
Method of measurement
Standard enzymatic method

9

Description
hepatic steatosis index(HS index)
Timepoint
At the beginning of the study and after the intervention (12 weeks after the start of the intervention)
Method of measurement
standard formula

10

Description
fatty liver index(FL index)
Timepoint
At the beginning of the study and after the intervention (12 weeks after the start of the intervention)
Method of measurement
standard formula

11

Description
triglyceride glucose index(TYG index)
Timepoint
At the beginning of the study and after the intervention (12 weeks after the start of the intervention)
Method of measurement
standard formula

12

Description
Alanin amino transferase
Timepoint
At the beginning of the study and after the intervention (12 weeks after the start of the intervention)
Method of measurement
Enzyme linked immuno sorbent assay(ELISA)

13

Description
Gamma-glutamyl transferase (GGT)
Timepoint
At the beginning of the study (before the intervention) and the end of the study (12 weeks after the intervention)
Method of measurement
Enzyme linked immuno sorbent assay(ELISA)

Intervention groups

1

Description
Intervention group: Daily intake of 30 grams of jujube powder(Shaina Sharq Jujube company)) for 12 weeks along with a low-calorie diet (500 kcal reduction)
Category
Treatment - Other

2

Description
Control group: Following a low-calorie diet (reduction of 500 kcal of energy intake) recommended by the researcher for 12 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Hazrat bolfazl Hospital
Full name of responsible person
Ronak Borzoei
Street address
gomrok st
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6715715516
Phone
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Email
ronakborzooie@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Abbas Ali Imani Fooladi
Street address
baqiatala university south sheikh baha st, molasadra, st , vanak sq.
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imanifouladi@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Bagheiat-allah 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
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Ronak Borzoei
Position
MSc Student
Latest degree
Bachelor
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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Position
MSC student

Latest degree
Bachelor

Other areas of specialty/work
Nutrition

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6715715516

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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