

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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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kermanshah

Province

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Abbas Ali Imani Fooladi

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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

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Maryam Taghdir

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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Name of organization / entity

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Position

MSC student

Latest degree

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Other areas of specialty/work

Nutrition

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Province

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Postal code

6715715516

Phone

+98 83 2182 4025

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