

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of Beta vulgaris total extract effect on improvment of non-alcoholic fatty live disease factors

Protocol summary

Study aim

The effect of Beta vulgaris extract on improvement of liver parameters in patients with non-alcoholic fatty liver

Design

randomized, double blinded, parallel group clinical trial with control group , 120 subjects

Settings and conduct

Patients referred to the gastroenterology clinic of Shahid Beheshti Hospital of Kashan with a diagnosis of non-alcoholic fatty liver, which patients and physicians do not know about medicine or placebo.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 18 to 70 years old; non-alcoholic fatty liver diagnosis. Exclusion criteria: pregnancy and lactation; alcohol consumption; addiction; diabetes; cirrhosis and hepatitis.

Intervention groups

Intervention group: Prescribing Beta Vulgaris Extract
Control group: Placebo administration

Main outcome variables

Recovery of liver enzymes and fatty liver in ultrasound

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20121017011145N20**
Registration date: **2018-05-18, 1397/02/28**
Registration timing: **registered_while_recruiting**

Last update: **2018-05-18, 1397/02/28**

Update count: **0**

Registration date

2018-05-18, 1397/02/28

Registrant information

Name

Mohammad Reza Sharif

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 5554 0026

Email address

sharif_m@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-02-20, 1396/12/01

Expected recruitment end date

2018-08-23, 1397/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Beta vulgaris total extract effect on improvment of non-alcoholic fatty live disease factors

Public title

Evaluation of Beta vulgaris total extract effect on improvment of non-alcoholic fatty live disease factors

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18-70 years old Non-alcoholic fatty live disease diagnosis

Exclusion criteria:

Pregnancy and lactation alcohol consumption Drug addiction Diabetes mellitus, cirrhosis, hepatitis

Age

From **18 years** old to **70 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization method: Simple randomization
Random unit: Individual Randomization Tool: Random Numbers

Blinding (investigator's opinion)
Double blinded

Blinding description
All patients, physicians and statisticians are unaware of the type of medicine or placebo.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tehran University of Medical Sciences

Street address
Enghelab St.

City
Tehran

Province
Tehran

Postal code
1417653761

Approval date
2017-11-18, 1396/08/27

Ethics committee reference number
IR.TUMS.PSRC.REC.1396.4044

Health conditions studied

1

Description of health condition studied
Non – alcoholic fatty live disease

ICD-10 code

K76.1

ICD-10 code description
Other specified inflammatory liver diseases

Primary outcomes

1

Description
Liver aminotransferases

Timepoint
Before starting treatment, three and six months after starting treatment

Method of measurement
ELISA test

2

Description
The severity of fatty liver

Timepoint
Before starting treatment, three and six months after starting treatment

Method of measurement
Liver ultrasound

Secondary outcomes

1

Description
Fasting Blood Glucose, Triglycerides, and Cholesterol

Timepoint
Before the intervention, three and six months after the intervention

Method of measurement
Biochemical laboratory tests

Intervention groups

1

Description
Intervention group: Beta-vulgaris extract capsule 400 mg daily (Institute of Medicinal Plants, Iran) for 6 months

Category
Treatment - Drugs

2

Description
Control group: Placebo capsule daily (Institute of Medicinal Plants, Iran) for 6 months

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

بیمارستان شهید بهشتی

Full name of responsible person

Hasan Afzali

Street address

Ghotbe Ravandi Blvd

City

Kashan

Province

Isfahan

Postal code

8715981151

Phone

+98 31 5554 0026

Fax

+98 31 5554 8900

Email

hasanafsali@yahoo.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraian

Street address

Enghelab street

City

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 8163 3685

Fax

+98 21 8163 3623

Email

rmo@tums.ac.ir

Web page address<http://vcr.tums.ac.ir>**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tehran 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**

Kashan University of Medical Sciences

Full name of responsible person

Hasan Afzali

Position

professor

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

Street address

Ghotbe Ravandi Blvd

City

Kashan

Province

Isfahan

Postal code

8715981151

Phone

+98 31 5554 0026

Fax

+98 31 5554 8900

Email

hasanafsali@yahoo.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Kashan University of Medical Sciences

Full name of responsible person

Hasan Afzali

Position

professor

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

Street address

Ghotbe Ravandi Blvd

City

Kashan

Province

Isfahan

Postal code

8715981151

Phone

+98 31 5554 0026

Fax

+98 31 5554 8900

Email

hasanafsali@yahoo.com

Person responsible for updating data**Contact****Name of organization / entity**

Kashan University of Medical Sciences

Full name of responsible person

Hasan Afzali

Position

hasanafsali@yahoo.com

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

Street address

Ghotbe Ravandi Blvd

City

Kashan

Province

Isfahan

Postal code

8715981151

Phone

+98 31 5554 0026

Fax

+98 31 5554 8900

Email

hasanafsali@yahoo.com

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