

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Comparison of the effect of Rosa damascena with placebo on liver enzymes in patients with nonalcoholic fatty liver disease (NAFLD): a double-blind randomized clinical trial

Protocol summary

Study aim

Comparison of the effect of Rosa damascena with placebo on liver enzymes in patients with nonalcoholic fatty liver disease (NAFLD): a double-blind randomized clinical trial

Design

Clinical trial with placebo, parallel groups, double blind, randomized

Settings and conduct

In this double-blind clinical trial, the effect of placebo on liver enzymes in non-alcoholic fatty liver patients was evaluated. Patients are randomly divided into two groups of case and control. Liver enzymes (ALT, AST) were measured at baseline and 12th week. Both groups received dietary and exercise recommendations alike. Case group receive 3 grams Rosa damascena per day and the control group receive 3 grams of placebo daily capsules 500 mg. The drug and placebo are coded in similar capsules and in identical packages, with the same color and aroma, and the patient, clinician, and researcher are unaware of how the drug or placebo is coded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Non Alcoholic Fatty Liver Disease (NAFLD) patients with liver enzymes rising (AST > 31, ALT > 38) and sonographic report grade 1 & 2 & 3 of fatty liver. Age between 12 - 80 years old
Exclusion criteria: Patient dislike to enter this study; Pregnancy & lactation; Anti coagulant drugs consumption; Thyroid diseases; Spleen diseases Cirrhosis, viral hepatitis and obstructive disease of liver; Under treatment dyslipidemia; Overt D.M; Lung diseases; History of Alcoholism; Consumption of any drug that affects on liver enzymes and liver metabolism such as OCP, corticosteroids, salazins and ext.

Intervention groups

Intervention group: Rosa damascena, 3 grams daily,,

Orally, For 12 weeks Control group: Placebo (Sokhari powder) 3 grams daily, Orally, For 12 weeks

Main outcome variables

Comparison of changes in liver enzymes (ALT, AST) in non-alcoholic fatty liver patients in drug and placebo groups before and after the study

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191006044994N1**

Registration date: **2019-11-11, 1398/08/20**

Registration timing: **prospective**

Last update: **2019-11-11, 1398/08/20**

Update count: **0**

Registration date

2019-11-11, 1398/08/20

Registrant information

Name

Seyed Ali -Alhadi Moravej

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7752 1303

Email address

alimoravej713@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-19, 1398/08/28

Expected recruitment end date

2020-06-20, 1399/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Rosa damascena with placebo on liver enzymes in patients with nonalcoholic fatty liver disease(NAFLD): a double-blind randomized clinical trial

Public title

Effect of Rosa damascena on nonalcoholic fatty liver disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Sonographic report of Grade 1- 2-3 fatty liver Increase in ALT> 38, Increase in AST>31 Ages 12 to 80 years Ages 18 to 80 years

Exclusion criteria:

The patient's unwillingness to participate in the scheme Pregnancy & lactation Anti coagulant drugs consumption Thyroid diseases Spleen diseases Cirrhosis ,viral hepatitis and obstructive liver diseae Treated dyslipidemia Overt Diabetes mellitus Lung diseases Taking any medication that affects liver metabolism and enzymes, including oral contraceptives, corticosteroids, salazines, etc.

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

The block randomization method is used using 4-way blocks and a random number table. Interventions A and B define six blocks of four. Using random numbers, we select and write blocks. Each individual is then assigned to an A or B intervention. For allocation concealment, sealed envelopes are used, so that the individual number is written on the envelope and the treatment group inside the envelope.

Blinding (investigator's opinion)

Double blinded

Blinding description

The drug and placebo are coded in similar capsules and in identical packages, with the same color and aroma, and the patient, clinician, and researcher are unaware of

how the drug or placebo is coded.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

No. 167, Mojahedine Eslam Ave., Behnam Towers

City

Tehran

Province

Tehran

Postal code

1154838346

Approval date

2019-07-16, 1398/04/25

Ethics committee reference number

IR.IUMS.REC.1398.406

Health conditions studied

1

Description of health condition studied

Non Alcoholic Fatty Liver Disease

ICD-10 code

k76.0

ICD-10 code description

Non Alcoholic Fatty Liver Disease

Primary outcomes

1

Description

Alt(Alanin transaminase)

Timepoint

Onset and 12th week of study(End of study)

Method of measurement

Hitachi-912 biochemistry instrument

2

Description

Ast(Aspartate transaminase)

Timepoint

Onset and 12th week of study(End of study)

Method of measurement

Hitachi-912 biochemistry instrument

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 500 mg capsules of Rosa damascena,6 capsules per day ;each time 2 capsules(*3), Orally, For12 weeks

Category

Treatment - Drugs

2

Description

Control group: Placebo (breadcrumbs), 500 mg capsule containing breadcrumbs, 6 capsules daily, three per day each time 2 capsules, orally for 12 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat-Rasool hospital

Full name of responsible person

Seied Alihadi Moravej

Street address

No.167, Behnam Towers, Mojahedhne Eslam Ave.

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2

Recruitment center

Name of recruitment center

Behesht Persian Medicin clinic

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Seyed Abbas Motevalian

Street address

Shahid Hemmat Highway, Iran University of Medical Science.

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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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Seyed Alihadi Moravej

Position

Resident

Latest degree

Specialist

Other areas of specialty/work

Traditional Medicine

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information.

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