

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Aug 2026

Survey the Effect of celery seed on serum levels of hepatic enzymes, lipid profile, glycemic parameters and hepatic steatosis degree in nonalcoholic fatty liver disease patients, with overweight and obesity

Protocol summary

Study aim

Effect of celery seed supplementation on serum levels of liver enzymes (AST, ALT), lipid profile (VLDL HDL, LDL, TG), glycemic index and degree of hepatic steatosis in obese and overweight non-alcoholic fatty liver patients

Design

In this double-blind, single-center clinical trial study, 44 patients with nonalcoholic fatty liver were randomly divided into two groups of 22 intervention and control group. Randomization occurs by blocking.

Settings and conduct

This study is performed on people with non-alcoholic fatty liver referred to gastrointestinal clinic in Ahvaz. Researchers and patients will not be aware of how they are randomly assigned to groups (double blind). Before and after the study, liver enzymes and lipid profiles and fasting blood glucose and insulin levels and hs-CRP and anthropometric measurements were measured.

Participants/Inclusion and exclusion criteria

Overweight and obese patients (with BMI > 25) with nonalcoholic fatty liver (grade 1, 2) having ultrasound sheet with diagnosis of nonalcoholic fatty liver with radiologist and gastroenterologist approval

Intervention groups

The intervention group received 4 capsules daily of 500 mg celery seed for 6 weeks. The control group received 4 placebo 500 mg starch capsules daily.

Main outcome variables

Fasting blood sugar, hepatic enzymes (ALT, AST), lipid profile (TG, Chol, HDL, VLDL), serum insulin, Insulin resistance index, Hs-CRP

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191124045488N1**

Registration date: **2019-11-29, 1398/09/08**

Registration timing: **prospective**

Last update: **2019-11-29, 1398/09/08**

Update count: **0**

Registration date

2019-11-29, 1398/09/08

Registrant information

Name

Mahsa Samadani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3648 0181

Email address

samadani.m@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-07, 1398/09/16

Expected recruitment end date

2020-03-10, 1398/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Survey the Effect of celery seed on serum levels of hepatic enzymes, lipid profile, glycemic parameters and hepatic steatosis degree in nonalcoholic fatty liver

disease patients, with overweight and obesity

Public title
effect of celery seed on obesity and fatty liver

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Overweight and obese patients (with BMI> 25) With nonalcoholic fatty liver (grade 1, 2) having ultrasound sheet with diagnosis of nonalcoholic fatty liver with radiologist and gastroenterologist approval
Exclusion criteria:
 Pregnancy and lactation liver transplantation cigarette smoking, alcohol and drugs use medications such as corticosteroids, amiodarone, tamoxifen, prazacillin, methotrexate complete intravenous nutrition heart failure, kidney disease, thyroid failure Hemochromatosis and Wilson disease Having positive test for hepatitis C, B and autoimmune hepatitis alpha-antitrypsin deficiency

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

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **44**

Randomization (investigator's opinion)
Randomized

Randomization description
 44 subjects were divided into two groups of 22 intervention and control groups based on the block design method. In this way, an out-of-study third person who is familiar with health issues gives the supplement and placebo the same two codes as A and B. Subsequently, individuals are assigned AAB and BBAA. There are actually two 4-block blocks, each block having two A codes and two B codes. People are given codes in order to reach number 8, and repeat this number until they reach number 16. Then one of the blocks is repeated again to reach 20. Then the remaining two people receive a random code A or B code that reaches 22 people.

Blinding (investigator's opinion)
Double blinded

Blinding description
 In this study, the researcher and the participants are kept blind, and the third person oversees the intervention and control groups outside the study.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Faculty of Paramedical Sciences, Golestan Boulevard, Jundishapur University of Medical Sciences

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Approval date

2019-11-23, 1398/09/02

Ethics committee reference number

IR.AJUMS.REC.1398.620

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

Hepatic enzymes (AST, ALT)

Timepoint

Before and after intervention

Method of measurement

Use of enzymatic kits

2

Description

Lipid profile (Triglyceride, total cholesterol, LDL, VLDL, HDL)

Timepoint

Before and after intervention

Method of measurement

Use of enzymatic kits

3

Description

Insulin levels

Timepoint

Before and after intervention

Method of measurement

Use of enzymatic kits

4**Description**

Liver Echogenicity

Timepoint

Before and after intervention

Method of measurement

Using an ultrasound machine by a radiologist

5**Description**

The total amount of calorie received

Timepoint

Before and after intervention

Method of measurement

Using a 24-hour food recording questionnaire

6**Description**

hs-CRP

Timepoint

Before and after intervention

Method of measurement

Use of enzymatic kits

7**Description**

Body fat percentage

Timepoint

Before and after intervention

Method of measurement

Using body composition measuring device

8**Description**

weight

Timepoint

Before and after intervention

Method of measurement

Using digital scales

9**Description**

Waist and hip circumference

Timepoint

Before and after intervention

Method of measurement

Use non-elastic tape meters

10**Description**

Fasting Blood sugar

Timepoint

Before and after intervention

Method of measurement

Use of enzymatic kits

11**Description**

HOMA-IR

Timepoint

Before and after intervention

Method of measurement

$HOMA-IR = BS(mmol/lit) \times insulin(microunit/lit) / 22.5$

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: getting 4 capsule of celery seed (500mg) per day for 6 weeks.

Category

Other

2**Description**

Control group: getting 4 capsules of placebo for 6 weeks.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

private clinic

Full name of responsible person

Seyed Saeed Seyedian

Street address

West Pahlevan Ave.

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Phone

+98 61 3373 8253

Fax

+98 61 3373 8253

Email

seyedian-ss@ajums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mohammad Badavi

Street address

Golestan boulevard, Jundishapour University of medical sciences

City

Ahvaz

Province

Khouzestan

Postal code

61357-15794

Phone

+98 61 3336 2414

Fax

+98 61 3336 1544

Email

itc@ajums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Ahvaz 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**

Ahvaz University of Medical Sciences

Full name of responsible person

Mahsa Samadani

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

Street address

Golestan Boulevard, Jundishapour University of medical sciences, Faculty of Paramedical Sciences

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Phone

+98 71 3648 0181

Fax**Email**

samadani.m@ajums.ac.ir

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Majid Mohammad Shahi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Golestan Boulevard, Jundishapour University of medical sciences, Faculty of Paramedical Sciences

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Phone

+98 71 3648 0181

Fax**Email**

mohamadshahi-m@ajums.ac.ir

Web page address

Person responsible for updating data

Contact**Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Mahsa Samadani

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

Street address

Golestan Boulevard, Jundishapour University of medical sciences, Faculty of Paramedical Sciences

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Phone

+98 71 3648 0181

Fax**Email**

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

Due to the financial support of this research project by Ahvaz Jundishapur University of Medical Sciences, the study data will not be allowed to be published after the intervention.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available