

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 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

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##### 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 AABB 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**

Khuzestan

**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 fo 6 weeks.

**Category**

Other

**2****Description**

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

**Category**

Placebo

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

private clinic

**Full name of responsible person**

Seyed Saeed Seyedian

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West Pahlevan Ave.

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**Sponsors / Funding sources**

## 1

### Sponsor

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Mohammad Badavi

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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**

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

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### Person responsible for scientific inquiries

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Associate professor

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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**

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