Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Nov 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
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Mahsa Samadani
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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, pracacillin, 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, Jundishapour 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 cholesterole, 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)×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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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 updating data

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Other areas of specialty/work
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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