Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Nov 2026

the Effect of Stevia Dry Leaves on Serum Levels of Liver Enzymes, Lipid Profile, Glycemic Indicators, Adiponectin and Leptin in Overweight and Obese Diabetic Patients with Non-Alcoholic Fatty Liver

Protocol summary

Study aim

the Effect of Stevia Dry Leaves on Serum Levels of Liver Enzymes, Lipid Profile, Glycemic Indicators, Adiponectin and Leptin in Overweight and Obese Diabetic Patients with Non-Alcoholic Fatty Liver

Design

The present study is a Phase 3 clinical trial, double-blind, and parallel, on 50 diabetic patients with overweight and obese fatty liver who have criteria for entering the study. The random numbers table is divided into two groups of intervention and control and each person is assigned a code.

Settings and conduct

This study was performed on diabetic patients with overweight and obesity and fatty liver, referred to Soroush specialized clinic in Ahvaz, Khuzestan province. At the beginning and the end of the study, fasting blood samples will be taken to evaluate lipid, glycemic, leptin, and adiponectin profiles. Physical diet and physical activity will be recorded by dietary intake and physical activity questionnaire.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Overweight and obese diabetic patients with non-alcoholic fatty liver (Grade 1, 2 and 3) having an ultrasound sheet with a non-alcoholic fatty liver diagnosis with a approved gastroenterologist in the range of 20 to 60 years of ageradiologist and an Non-inclusion criteria: pregnancy and lactation؛ liver transplantation; hereditary hematocromatosis and Wilson; positive test for hepatitis C, B and autoimmune hepatitis

Intervention groups

Intervention group: 2 capsules of 250 mg of stevia dry leaves for 8 weeks Control group: 2 capsules of 250 mg starch per day for 8 weeks

Main outcome variables

Fasting Glucose; Insulin; Insulin Resistance; Lipid Profile; Leptin ; Serum Adiponectin; and Liver Enzymes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181119041701N1**
Registration date: **2019-07-05, 1398/04/14**
Registration timing: **retrospective**

Last update: **2019-07-05, 1398/04/14**
Update count: **0**

Registration date

2019-07-05, 1398/04/14

Registrant information

Name
Reyhaneh Mazrae
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-21, 1397/11/01

Expected recruitment end date

2019-06-22, 1398/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
the Effect of Stevia Dry Leaves on Serum Levels of Liver Enzymes, Lipid Profile, Glycemic Indicators, Adiponectin and Leptin in Overweight and Obese Diabetic Patients with Non-Alcoholic Fatty Liver

Public title
The effect of dried leaves of Stevia in the treatment of diabetes, non-alcoholic fatty liver and obesity

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Diabetic patients Overweight and obese Non-alcoholic fatty liver Having an ultrasound sheet with a diagnosis of non-alcoholic fatty liver In the age range of 20 to 60 years

Exclusion criteria:
Pregnancy and lactation liver transplantation smoking, alcohol and drugs complete intake of venous heart failure kidney diseases hereditary hematocromatosis and Wilson Having a positive test for hepatitis C, B and autoimmune hepatitis

Age
From **20 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization، Use random numbers Table

Blinding (investigator's opinion)
Double blinded

Blinding description
The type of blindness in our study will be double-blind. Prior to the onset of the study, the box containing the relevant pills are coded A and B by an individual except the researcher, in order to blind the researcher about which supplement each group received. When delivering supplements to patients, some one except the researcher should locate the patient in either A or B group by random number table. In this study, the patients and researcher (who collecting data, assessing the outcome and analyzing the data) should be kept blind.

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
Vice chancellor for research and technology, Ahvaz Jundishapur University of Medical Sciences, Shahre Daneshgahi

City
Ahvaz

Province
Khouzestan

Postal code
6135715794

Approval date
2019-01-20, 1397/10/30

Ethics committee reference number
IR.AJUMS.REC.1397.778

Health conditions studied

1

Description of health condition studied
Diabetes

ICD-10 code
E11.9

ICD-10 code description
Type 2 diabetes mellitus without complications

2

Description of health condition studied
Non-alcoholic fatty liver

ICD-10 code
K76.0

ICD-10 code description
Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description
Lipid profile

Timepoint
Before and after 8 weeks of intervention

Method of measurement
Laboratory test

2

Description
Liver Enzymes

Timepoint
Before and after 8 weeks of intervention
Method of measurement
Laboratory test

3

Description
Fasting blood sugar
Timepoint
Before and after 8 weeks of intervention
Method of measurement
Laboratory test

4

Description
Insulin resistance
Timepoint
Before and after 8 weeks of intervention
Method of measurement
Using the HOMA-IR formula

5

Description
Leptin
Timepoint
Before and after 8 weeks of intervention
Method of measurement
Laboratory test

6

Description
Adiponectin
Timepoint
Before and after 8 weeks of intervention
Method of measurement
Laboratory test

7

Description
Body mass index
Timepoint
Before and after 8 weeks of intervention
Method of measurement
The weight ratio in kilograms to the second power of height in meters

Secondary outcomes

1

Description
Systolic blood pressure
Timepoint
Before and after 8 weeks of intervention
Method of measurement
Mercury pressure gauge

2

Description
diastolic blood pressure
Timepoint
Before and after 8 weeks of intervention
Method of measurement
Mercury pressure gauge

Intervention groups

1

Description
Intervention group: Everyone will receive 2 capsules 250 mg stevia per day for 8 weeks
Category
Treatment - Drugs

2

Description
Control group: Everyone will receive placebo, starch, 2 capsules 250 mg per day for 8 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Soroush Special Clinic
Full name of responsible person
Dr. Pejman Alavinejad
Street address
West Soroush Avenue, Kianpars
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Reyhaneh Mazrae
Position
Master's Degree in Nutrition Sciences
Latest degree
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Person responsible for updating data

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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