# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

25 Jun 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)
**Phone**
+98 61 3335 1511
**Email address**
mazrae.r@ajums.ac.ir

**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
**City**
Ahvaz
**Province**
Khouzestan
**Postal code**
61357-15794
**Phone**
+98 61 3333 7908
**Email**
Mazrae.r@ajums.ac.ir

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Ahvaz University of Medical Sciences
**Full name of responsible person**
Dr. Mohammad Badvi
**Street address**
Vice chancellor for research and technology, Ahvaz Jundishapur University of Medical Sciences, Golestan Ave.

**City**
Ahwaz
**Province**
Khouzestan
**Postal code**
61357-15794
**Phone**
+98 61 3336 7570
**Fax**
+98 61 3336 1544
**Email**
badavi-m@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**
Reyhaneh Mazrae
**Position**
Master's Degree in Nutrition Sciences
**Latest degree**
Bachelor
**Other areas of specialty/work**
Nutrition
**Street address**
Golestan Highway
**City**
Ahwaz
**Province**
Khouzestan
**Postal code**
61357-15794
**Phone**
+98 61 3373 8383
**Email**
Mazrae.r@gmail.com

## 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 of Nutrition
**Latest degree**
Ph.D.
**Other areas of specialty/work**
Nutrition
**Street address**
Department of Nutrition, Faculty of Paramedicine, Jundishapur University of Medical Sciences, Golestan Ave.
**City**
Ahwaz
**Province**
Khouzestan
**Postal code**
61357-15794
**Phone**
+98 61 3373 8317
**Email**
mohamadshahi-m@ajums.ac.ir

## Person responsible for updating data

**Contact**

**Name of organization / entity**
Ahvaz University of Medical Sciences
**Full name of responsible person**
Reyhaneh Mazrae
**Position**
Masters of Nutrition
**Latest degree**
Bachelor
**Other areas of specialty/work**
Nutrition
**Street address**
Department of Nutrition, Faculty of Paramedicine, Ahwaz, Golestan Ave., Jundishapur University of Medical Sciences, Ahvaz, Iran.
**City**
Ahwaz
**Province**
Khouzestan
**Postal code**
61357-15794
**Phone**
+98 61 3373 8383
**Email**
Mazrae.r@ajums.ac.ir

## 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