

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effects of freeze - dried strawberry powder on glucose and lipid profile, malondialdehyde (MDA), hs-CRP and serum total antioxidant capacity in type 2 diabetic patients

#### Protocol summary

##### Summary

The aim of this randomized double blind clinical trial is to determine the effects of freeze dried strawberry consumption on some blood biochemical parameters in type 2 diabetic patients. Forty patients aged between 30-60 years old from both sexes are assigned into two groups. Patients in intervention group consume 2 cups of freeze dried strawberry beverage (50 g /day) and patients in control group consume 2 cups of placebo beverage with strawberry flavor (8g pectin and 24g lactose) for 6 weeks. Anthropometric and blood pressure measurements, 3-day 24h dietary recalls and fasting blood samples are collected at the beginning and at the end of study. Fasting blood sugar, glycosylated hemoglobin, lipid profile, malondialdehyde, total antioxidant capacity, and high sensitive C-reactive protein are measured. The participants are asked not to change their regular diet, medicine and activity during the study and refrain from other sources of berries, green tea, cocoa, and soy products while on the study.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201110117765N1**

Registration date: **2012-08-02, 1391/05/12**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2012-08-02, 1391/05/12

##### Registrant information

##### Name

Sara Moazzen

##### Name of organization / entity

Ahvaz Joundishapour University of Medical Science

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1380 1454

##### Email address

moazzen.s@ajums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Ahvaz Joundishapour University of Medical Science

##### Expected recruitment start date

2011-04-10, 1390/01/21

##### Expected recruitment end date

2012-05-30, 1391/03/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effects of freeze - dried strawberry powder on glucose and lipid profile, malondialdehyde (MDA), hs-CRP and serum total antioxidant capacity in type 2 diabetic patients

##### Public title

Effect of strawberry powder on diabetes complications

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

Inclusion criteria: Having type 2 diabetes; 30 to 60 years old; LDL level more than 100 mg/DL. Exclusion criteria: Having renal or hepatic failure; cardiovascular disease; thyroid disorders; lactose intolerance; treatment with

insulin; taking corticosteroides, NSAIDS, cholesterol lowering drugs, multivitamin-mineral and fiber supplements; BMI more than 35 Kg/m2; smoking; pregnancy and lactation; use of multivitamin-mineral and fiber and antioxidant supplements 3 weeks prior to the study.

#### **Age**

From **30 years** old to **65 years** old

#### **Gender**

Both

#### **Phase**

N/A

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **40**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Double blinded

#### **Blinding description**

#### **Placebo**

Used

#### **Assignment**

Parallel

#### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### **1**

#### **Ethics committee**

##### **Name of ethics committee**

Ethics committee of Ahvaz Joundishapour University of Medical Science

##### **Street address**

Glestan street

##### **City**

Ahvaz

##### **Postal code**

#### **Approval date**

2012-03-11, 1390/12/21

#### **Ethics committee reference number**

ETH\_393

## **Health conditions studied**

### **1**

#### **Description of health condition studied**

None-insulin dependant diabetease mellistus

#### **ICD-10 code**

E11

#### **ICD-10 code description**

Non-insulin-dependent diabetes mellitus

## **Primary outcomes**

### **1**

#### **Description**

Fasting Blood Sugar

#### **Timepoint**

baseline and after 6 weeks

#### **Method of measurement**

spectrophotometry

### **2**

#### **Description**

Hemoglobin A1c

#### **Timepoint**

baseline and after 6 weeks

#### **Method of measurement**

Chromatography

### **3**

#### **Description**

Total Cholesterol

#### **Timepoint**

Baseline and after 6 weeks

#### **Method of measurement**

Spectrophotometry

### **4**

#### **Description**

Triglyceride

#### **Timepoint**

Baseline and after 6 weeks

#### **Method of measurement**

Spectrophotometry

### **5**

#### **Description**

LDL

#### **Timepoint**

Baseline and after 6 weeks

#### **Method of measurement**

Friedewald Formula

### **6**

#### **Description**

HDL

#### **Timepoint**

Baseline and after 6 weeks

#### **Method of measurement**

Spectrophotometry

### **7**

#### **Description**

Malondialdehyde

#### **Timepoint**

Baseline and after 6 weeks

#### **Method of measurement**

Spectrophotometry

**8**

**Description**

Total Antioxidant Capacity (TAC)

**Timepoint**

Baseline and after 6 weeks

**Method of measurement**

Spectrophotometry

**9**

**Description**

hsCRP

**Timepoint**

Baseline and after 6 weeks

**Method of measurement**

Immunoturbidometry

**Secondary outcomes**

**1**

**Description**

Dietary Factors

**Timepoint**

Baseline and after 6 weeks

**Method of measurement**

3-day 24h dietary recalls

**2**

**Description**

Body Mass Index

**Timepoint**

Baseline and after 6 weeks

**Method of measurement**

Formula

**3**

**Description**

Blood Pressure

**Timepoint**

Baseline and after 6 weeks

**Method of measurement**

Sphygmomanometer

**Intervention groups**

**1**

**Description**

Intervention Group: 2 cups of strawberry beverage containing 50 gr of freeze dried strawberry daily for 6 weeks

**Category**

Treatment - Drugs

**2**

**Description**

Control Group: 2 cups of Placebo beverage, containing 32 gr of placebo powder ( containing 24 g lactose and 8 g pectin ), daily for 6 weeks

**Category**

Placebo

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Ahvaz Diabetes Research Center

**Full name of responsible person**

Dr Reza Amani

**Street address**

**City**

Ahvaz

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Ahvaz Joundishapour University of Medical Science

**Full name of responsible person**

Dr Reza Amani

**Street address**

Golestan street

**City**

Ahvaz

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Ahvaz Joundishapour University of Medical Science

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Para medicine Faculty, Ahvaz Joundishapour University of Medical Science

**Full name of responsible person**

Dr Reza Amani

**Position**

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**Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*