Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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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 diabetese 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
Immunotorbidometry

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
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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