

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

A comparison between replacement of diet beverage soft drinks with water on weight loss in obese and overweight healthy women.

Protocol summary

Summary

The purpose of this study is comparison between replacement of diet soda with water on weight loss in obese and overweight healthy women. This study is parallel randomized clinical trials. Sixty participant with Body Mass Index 27-35 kg/m² and age 18-50 years that consumes at least 250 calories per day (4-5 days/ week) from caloric beverages will be selected. Participants involving weight loss or physical activity in the previous 6 months, Additionally, report current participating in any other research studies whose results could be compromised by or in which participation could compromise this research study, report pregnancy or lactation, during the previous 6 months, or planned pregnancy in the next 6 months, report taking medication that could affect metabolism or change body weight report heart problems, chest pain, cancer within the last 5 years, unwilling to change intake of beverages during the study period will be excluded. Participants will be randomly divided in two groups: 1) substitute water for diet soda or 2) continue drinking diet soda five times per week. Subjects' weight are assessed before, after 12, 24 and 77 weeks of study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201402177754N5**

Registration date: **2014-03-11, 1392/12/20**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-03-11, 1392/12/20

Registrant information

Name

Leila Shafiei Neek

Name of organization / entity

Faculty of Physical Education and Sport Sciences,
University of Tehran

Country

Iran (Islamic Republic of)

Phone

+98 21 2258 9952

Email address

shafieineek@ut.ac.ir

Recruitment status

Recruitment complete

Funding source

Novin Diet Clinic

Expected recruitment start date

2014-04-21, 1393/02/01

Expected recruitment end date

2014-10-23, 1393/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison between replacement of diet beverage soft drinks with water on weight loss in obese and overweight healthy women.

Public title

Effects of replacement of diet beverage soft drinks with water on promoting weight reduction

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: 18-50 years of age; Body mass index between 27-35 kg/m²; Subject consumes at least 250 calories per day (4-5 days/ week) from caloric beverages.

Exclusion Criteria: Report participating in a research project involving weight loss or physical activity in the previous 6 months; Additionally, report current participating in any other research studies whose results could be compromised by or in which participation could compromise this research study; report pregnancy or lactation; during the previous 6 months, or planned pregnancy in the next 6 months; report taking medication that could affect metabolism or change body weight report heart problems; chest pain, cancer within the last 5 years; unwilling to change intake of beverages during the study period.

Age

From **18 years** old to **50 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Digestive Disease Research Institute

Street address

Shariati Hospital., North Kargar Ave.

City

Tehran

Postal code**Approval date**

2014-01-28, 1392/11/08

Ethics committee reference number

FWA00001331

Health conditions studied**1****Description of health condition studied**

Obesity

ICD-10 code

E66

ICD-10 code description

Obesity due to excess calories

Primary outcomes**1****Description**

Weight

Timepoint

first, after 12 , 24, 77 weeks

Method of measurement

scale

Secondary outcomes**1****Description**

Carbohydrate metabolism

Timepoint

first, after 12 , 24, 77 weeks

Method of measurement

Blood testing

2**Description**

Cardiometabolic risk factors

Timepoint

first, after 12 , 24, 77 weeks

Method of measurement

Blood testing

Intervention groups**1****Description**

in first group, water are replaced with diet soda and will follow a low calorie diet (Novin Diet protocol).

Category

Behavior

2**Description**

second group continued to receive the diet soda and will follow a low calorie diet (Novin Diet protocol).

Category

Behavior

Recruitment centers**1****Recruitment center**

Name of recruitment center

Novin Diet Clinic

Full name of responsible person

Dr. Haminreza Farshchi

Street address

No 5., 4th Floor., Nikan Bldg., Shariati Ave.,

City

Teharan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Novin Diet Clinic

Full name of responsible person

Dr. Hamidreza Farshchi

Street address

No.5, 4th Floor, Nikan Bldg, Shariati Ave

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Novin Diet Clinic

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

Novin Diet Clininc

Full name of responsible person

Dr.Seyedeh Ameneh Majd

Position

Pharmacologist

Other areas of specialty/work

Street address

No.5, 4th Floor, Nikan Bldg, Shariati Ave

City

Tehran

Postal code

Phone

+98 21 2226 3002

Fax

Email

amameneh@hotmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Novin Diet Clininc

Full name of responsible person

Dr.Hamidreza Farshchi

Position

Clinical Nutritionist & Metabolism

Other areas of specialty/work

Street address

No.5, 4th Floor, Nikan Bldg, Shariati Ave

City

Tehran

Postal code

Phone

+98 21 2226 3002

Fax

Email

hrfarshchi@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Novin Diet Clinic

Full name of responsible person

Leila Shafiei Neek

Position

PhD student of exercise physiology

Other areas of specialty/work

Street address

No. 5, 4th Floor, Nikan Bldg, Shariati Ave

City

Tehran

Postal code

Phone

+98 21 2226 3002

Fax

Email

shafieineek@gmail.com

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