

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Effects of rapid or slow weight loss on body composition and metabolic risk factors in obese and overweight individuals

Protocol summary

Summary

(1) objectives: The aim of this clinical trial study is to evaluate the effects of glycemic and lipid parameters of the two protocols on WL in obese and overweight people. (2) Design: In the beginning, individuals have been selected from a nutrition clinic (Ahvaz, Iran). The initial screening had been done after a brief explanation of the study, and preliminary evaluation had been done by phone. After that a meeting with complete description of the protocol and justification for the study has been done for volunteers. The final screening was carried out in accordance with inclusion and exclusion criteria. (3) Setting and conduct: Eligible individuals after filing the consent form have been divided randomly into two groups: rapid and slow weight loss (WL). Prior to WL, an ambulatory period was imposed for each subject to insure stabilization of body weight (± 2 kg during 4 weeks). During the body weight stabilization, a 3-day food dietary records was used to determine an individual's daily food and beverage consumption to estimate their total daily caloric intake. The subjects have been randomly divided into two groups (Rapid WL and Slow WL). (4) Participants including major eligibility: Inclusion criteria were: lack of physical activity, no smoking, no alcohol drinking, no usage of herbal supplements and vitamins, and lack of weight changes in the last 6 months. Exclusion criteria included pregnancy and breastfeeding, use of drugs for metabolism, lipid and glycemic profile affects, diabetes, cardiovascular disease, kidney problems, thyroid, digestive, and respiratory diseases and cancer. (5) Interventions: Rapid WL and slow WL based on the lost weight (at least 5 %) have been defined over a period of 5 weeks and 15 weeks, respectively. The prescribed low calorie diet contained 15% as protein, 30 to 35% as fat and 50 to 55% as carbohydrate. (6) Main outcome measures: At the end of the study, anthropometric and biochemical assessments have been conducted on individuals who reached desired WL.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016010424699N2**

Registration date: **2016-05-08, 1395/02/19**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-05-08, 1395/02/19

Registrant information

Name

Damoon Ashtary-Larky

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 614436106

Email address

ashtary.d@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

This project supports by a grant from Ahvaz Jundishapur University of Medical Sciences.

Expected recruitment start date

2014-07-05, 1393/04/14

Expected recruitment end date

2015-10-20, 1394/07/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of rapid or slow weight loss on body composition and metabolic risk factors in obese and overweight individuals

Public title

Effects of rapid or slow weight loss on body composition and metabolic risk factors

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: age of 20-60; BMI= 25-40 or percentage of body fat more than 25% for men and 35% for women; don't taking the glucose and lipid- lowering drugs; interesting in participation in research; without any metabolic disease; CHD; diabetes; without autoimmune disease; cancer; without infection disease in research; no smoking; no alcoholism; without immune system suppressor drugs 6 mounts before research; no menstrual bleeding; without any diet 3 mounts before research; no consumption multivitamin mineral supplementation 3 mounts before research; women without polycystic ovary syndrome. Exclusion criteria: metabolic; CHD; autoimmune disease and cancer; infection disease in research; smoking; alcoholism; use of immune system suppressor drugs 6 mounts before research; menstrual bleeding; diet 3 mounts before research; consumption and multivitamin mineral supplementation 3 mounts before research; women with polycystic ovary syndrome; no interesting for participation.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **68**

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**

Medical Ethical Committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Ahvaz Jundishapur University of Medical Sciences, Golestan, Ahvaz

City

Ahvaz

Postal code**Approval date**

2015-06-20, 1394/03/30

Ethics committee reference number

IR.AJUMS.REC.1394.212

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

obesity

ICD-10 code

Z71.3

ICD-10 code description

Dietary counselling and surveillance

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

Insulin

Timepoint

Before and after intervention

Method of measurement

ELISA - mcU/ml

2**Description**

FBS

Timepoint

Before and after intervention

Method of measurement

mg/dl - Enzymatic method

3**Description**

Lipid Profile

Timepoint

Before and after intervention

Method of measurement

mg/dl - Enzymatic method

4**Description**

Hs-CRP

Timepoint

Before and after intervention

Method of measurement

mg/dl - ELISA

5

Description

CBC

Timepoint

Before and after intervention

Method of measurement

Automated CBC analyzer

6

Description

Urine analysis

Timepoint

Before and after intervention

Method of measurement

Enzymatic method

7

Description

Blood pressure

Timepoint

Before and after intervention

Method of measurement

Blood pressure machine

8

Description

Anthropometric tests

Timepoint

Before and after intervention

Method of measurement

Body fat Analyzer

9

Description

Resting metabolic rate

Timepoint

Before and after intervention

Method of measurement

Indirect calorimetry

Secondary outcomes

empty

Intervention groups

1

Description

Slow weight loss: received low-calorie diets produced an energy deficit of 500–750 kilo calories per day that which reduced at least 5% of body weight over a period of 15 weeks.

Category

Treatment - Other

2

Description

Rapid weight loss: received low-calorie diets produced an energy deficit of 1000–1500 kilo calories per day that which reduced at least 5% of body weight over a period of 5 weeks.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Damoon Ashtray-Larky

Street address

Ahvaz Jundishapur University of Medical Sciences,
Golestan, Ahvaz

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Ahvaz Jundishapur
University of Medical Sciences

Full name of responsible person

Nader Saki

Street address

Vice chancellor for research, Ahvaz Jundishapur
University of Medical Sciences, Golestan, Ahvaz

City

Ahvaz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Ahvaz Jundishapur
University of Medical Sciences

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

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Damoon Ashtary-Larky

Position

Msc. student of clinical biochemistry

Other areas of specialty/work**Street address**

Ahvaz Jundishapur University of Medical Sciences,
Golestan, Ahvaz

City

Ahvaz

Postal code**Phone**

+98 614436106

Fax**Email**

damoon_ashtary@yahoo.com

Web page address**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Damoon Ashtary-Larky

Position

Msc. student of clinical biochemistry

Other areas of specialty/work**Street address**

Ahvaz Jundishapur University of Medical Sciences,
Golestan, Ahvaz

City

Ahvaz

Postal code**Phone**

00

Fax**Email****Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Meysam Alipour

Position

PhD student of nutrition

Other areas of specialty/work**Street address**

Ahvaz Jundishapur University of Medical Sciences,
Golestan, Ahvaz

City

Ahvaz

Postal code**Phone**

+98 614452376

Fax**Email**

meysam.aalipour@yahoo.com

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