Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jul 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 haven 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
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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
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Msc. student of clinical biochemistry
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Person responsible for scientific inquiries

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Person responsible for updating data

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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