

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Evaluation of effect of acarbose consumption on weight loosing in nondiabetic obese patients in Kerman

Protocol summary

Summary

This study was a double-blind randomized controlled clinical trial. From all obese patients referred to the endocrinology clinic of Afzalipour hospital and office for treatment, 66 non diabetic subjects were recruited to this study. Inclusion criteria were age equal or more than 18 years, willingness to participate in the study, BMI (weight[kg]/ height[m]²) between 25-35, no evidence of cardiovascular disease, diabetes, gastrointestinal disease (IBD, intestinal ulcers, bowel obstruction), liver disease and renal disease, no history of medication for lowering weight, women should not be pregnant or milking. The exclusion criteria were no desire to continue the treatment, development of renal, gastrointestinal and liver disease during treatment and beginning to utilize antihypertensive drugs such as β blocker and thiazides. At the beginning of study, the baseline characteristics of all selected subjects including height, weight, total cholesterol, and triglyceride (TG) and fasting blood glucose (FBS) were recorded. Patients were randomly assigned to receive acarbose or placebo. Randomization was performed centrally by a computer program with minimization for height, weight and BMI according to the study center. Treatment group was given acarbose pills (100mg) and other group took lactose contained placebo (100mg). Patients were given study medication 1.5 tablets daily for the first two weeks and 3 tablets per day afterwards. Subjects were evaluated every month for adverse effects, weight loss and BMI for five months. At the baseline and once every three months blood samples for FBS, TG and Cholesterol were taken from patients

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201011151774N3**

Registration date: **2010-12-29, 1389/10/08**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-12-29, 1389/10/08

Registrant information

Name

Mojgan Sanjari

Name of organization / entity

Kerman University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 34 1322 2506

Email address

msanjari@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Kerman medical university; Excir company

Expected recruitment start date

2009-03-21, 1388/01/01

Expected recruitment end date

2010-03-21, 1389/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of effect of acarbose consumption on weight loosing in nondiabetic obese patients in Kerman

Public title

acarbose effect on weight loseing

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria were age equal or more than 18 years, willingness to participate in the study, BMI (weight[kg]/height[m]²) between 25-35, no evidence of cardiovascular disease, diabetes, gastrointestinal disease (IBD, intestinal ulcers, bowel obstruction), liver disease and renal disease, no history of medication for lowering weight, women should not be pregnant or milking. The exclusion criteria were no desire to continue the treatment, development of renal, gastrointestinal and liver disease during treatment and beginning to utilize antihypertensive drugs such as β blocker and thiazides.

Age

From **18 years** old to **149 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **66**

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

Kerman medical university ethics committee

Street address

Kerman Jomhori ave. Kerman medical university

City

Kerman

Postal code

Approval date

2009-07-24, 1388/05/02

Ethics committee reference number

k/88/106

Health conditions studied

1

Description of health condition studied

overweight

ICD-10 code

E66.9

ICD-10 code description

Obesity, unspecified

Primary outcomes

1

Description

BMI

Timepoint

monthly

Method of measurement

meter and weighting scale

Secondary outcomes

1

Description

Fbs, TG, Cholesterol

Timepoint

every three month

Method of measurement

lab test

Intervention groups

1

Description

placebo three tablets daily

Category

Placebo

2

Description

acarbose tablet 100 mg three tablets daily

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Afzali Pour hospital

Full name of responsible person

Dr Akram Nakhaee

Street address

City

Kerman

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman medical university
Full name of responsible person
 Dr Hamid Najafipour
Street address
 Kerman, Kerman medical university
City
 Kerman
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
 Yes
Title of funding source
 Kerman medical university
Proportion provided by this source
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

2

Sponsor

Name of organization / entity
 Excir company
Full name of responsible person
 Romiia Javadi
Street address
 22, Rahmati alley, Valiasr Ave
City
 Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
 Yes
Title of funding source
 Excir company
Proportion provided by this source
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
 Kerman Medical university
Full name of responsible person
 Dr Akram Nakhaee
Position

general physician
Other areas of specialty/work
Street address
 Kerman ,Kerman Medical university
City
 Kerman
Postal code
Phone
 +98 34 1245 3189
Fax
Email
 anakheai@gmail.com
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
 kerman medical university
Full name of responsible person
 Dr Mojgan Sanjari
Position
 Endocrinologist
Other areas of specialty/work
Street address
 Kerman, Kerman Medical university
City
 Kerman
Postal code
Phone
 +98 34 1322 2250
Fax
Email
 msanjari@kmu.ac.ir
Web page address

Person responsible for updating data

Contact

Name of organization / entity
 Kerman Medical University
Full name of responsible person
 Dr Akram Nakhaee
Position
 general physician
Other areas of specialty/work
Street address
 Kerman, Kerman Medical University
City
 Kerman
Postal code
Phone
Fax
Email
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