Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

Study on the effects of co-administration of lipase inhibitor and Alpha-glucosidase inhibitor in control of weight in obese patient

Protocol summary

Study aim

Determining the Effect of Co-Prescribing Orlistat and Acrobats on Weight Control in Obese People

Design

A randomized clinical trial, blind, double blind, controlled clinical trials, and a sample of 90 subjects who had entered the study by simple sampling after obtaining consent, using a balanced block randomization with three blocks in three groups (30 subjects) Are placed. All three groups of multivitamin tablets (weekly one) to prevent fat-soluble vitamin deficiencies and 40 mg of dimethicone three times a day will improve the symptoms of bleeding from orlistat and daily acarbose for 6 months.

Settings and conduct

1- Calculation of BMI and measurement of FBS, TG, LDL, HDL, cholesterol and insulin before and after intervention. 2- Setting up a diet and training the diet appropriately by a nutrition expert 3- Distribution of drugs and body weight measurement, delivery of supplements and monitoring their use, registration of possible side effects of medication, diet and diet monitoring, and physical activity on the checklist on a monthly basis. The design is done at the Endocrine Research Center of Kerman University of Medical Sciences.

Participants/Inclusion and exclusion criteria

Inclusion criteria: aged 20 to 50 years / non-underlying disease and BMI> 30. Exclusion criteria: Cases of cardiovascular / gastrointestinal / malabsorption / hyperlipidemia or hypothyroidism / Cushing's disease / Previously diagnosed diabetes by a doctor or existing documentation

Intervention groups

1- Orlistat drug group (3 daily food supplements, 180 mg) 2- Orlistat-Acarbose group (60 mg orlistat 3 times a day with food, 25 mg acarbose three times daily at the start of meal) 3- Control group (multivitamin, weekly 1)

Main outcome variables

Age, sex, height, weight, BMI, FBS, LDL, HDL, TG, insulin, waist circumference, hip circumference, WHR

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090317001774N9**
Registration date: **2018-09-19, 1397/06/28**
Registration timing: **registered_while_recruiting**

Last update: **2018-09-19, 1397/06/28**
Update count: **0**

Registration date

2018-09-19, 1397/06/28

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

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-21, 1397/01/01

Expected recruitment end date

2019-03-21, 1398/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study on the effects of co-administration of lipase inhibitor and Alpha-glucosidase inhibitor in control of weight in obese patient

Public title

Study lipase inhibitor and Alpha-glucosidase inhibitor in control of weight in obese patient

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 20 to 50 years Lack of underlying illness BMI>30

Exclusion criteria:

Fasting Blood Glucose Over 250 Hemoglobin A1C higher than 9% Insulin therapy Chronic inflammatory disease Chronic complications of diabetes Pregnancy Lactation Liver Diseases Kidney Diseases Neurological diseases

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Data analyser

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

After obtaining consent, the patients are divided into three groups based on entering the study and the method of balanced block randomization with triple blocks. The first group received orlistat (three daily food supplements, 180 mg), the second group was orlistat-acarbose (orlistat 60 mg three times daily with food, 25 mg acarbose three times daily at the start of meal) and the group Control (multivitamin, weekly 1).

Blinding (investigator's opinion)

Double blinded

Blinding description

The blinding of groups is divided by the expert of the research center which is not involved in the implementation of the plan, and is kept in the dark envelope in the package until the end of the design and final analysis at the research center. According to the traditional use group, there is no possibility of blindness for the physician and the patient. But randomization is done in the form of a balanced block randomization in binary groups and four blocks, and the statistician is blind compared to the groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee Vice chancellor for Research and Technology of kerman university of medical scienc

Street address

Kerman, Vice chancellor for Research and Technology of University of Medical Sciences, Tahmasb Abad crossroads, the begining of Jahad Boulevard, the begining of Ebn-e-Sina street, In front of Besat clinic

City

kerman

Province

Kerman

Postal code

7619813159

Approval date

2017-03-13, 1395/12/23

Ethics committee reference number

IR.KMU.REC.1395.1001

Health conditions studied

1

Description of health condition studied

ICD-10 code

ICD-10 code description

2

Description of health condition studied

obesity

ICD-10 code

E66

ICD-10 code description

Overweight and obesity

Primary outcomes

1

Description

Blood glucose after 8 hours of fasting

Timepoint

Before intervention and 6 months after intervention

Method of measurement

Spectrophotometer

2

Description

Measuring low density lipoprotein in serum

Timepoint

Before intervention and 6 months after intervention

Method of measurement
Using an auto-analyzer method

3

Description
Measuring high density lipoprotein in serum
Timepoint
Before intervention and 6 months after intervention
Method of measurement
Using an auto-analyzer method

4

Description
Measuring blood cholesterol
Timepoint
Before intervention and 6 months after intervention
Method of measurement
Using an auto-analyzer method

5

Description
Measuring blood triglycerides
Timepoint
Before intervention and 6 months after intervention
Method of measurement
Using an auto-analyzer method

6

Description
Insulin measurement
Timepoint
Before intervention and 6 months after intervention
Method of measurement
Using ELISA test

Secondary outcomes

1

Description
Weight
Timepoint
Before intervention and 6 months after intervention
Method of measurement
Scales

2

Description
Height
Timepoint
Before intervention and 6 months after intervention
Method of measurement
meter

3

Description
Waist
Timepoint
Before intervention and 6 months after intervention
Method of measurement
meter

4

Description
Hip circumference
Timepoint
Before intervention and 6 months after intervention
Method of measurement
meter

5

Description
BMI
Timepoint
Before intervention and 6 months after intervention
Method of measurement
The squared height is divided by weight

6

Description
WHR
Timepoint
Before intervention and 6 months after intervention
Method of measurement
Computing

Intervention groups

1

Description
First Intervention group: The recipient of Orlistat (three daily food supplements, 180 mg) for 6 months
Category
Treatment - Drugs

2

Description
Second Intervention group: The recipient of Orlistat and Acarbose (Orlistate 60mg 3 times daily with food, 25mg acarbose three times daily at the start of meal) for 6 months
Category
Treatment - Drugs

3

Description
Control group: placebo (Multivitamin, weekly 1) for 6 months
Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Besat Clinic

Full name of responsible person
Dr. Mojgan Sanjari

Street address
Besat Clinic, Ebne sina Ave, Jahad Blvd, Kerman, Iran

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7616913555

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
Dr.Abbas Pardakhti

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abpardakhty@kmu.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Kerman University of Medical Sciences

Proportion provided by this source
50

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Qazvin University of Medical Sciences

Full name of responsible person
Dr.Ehsan Aali

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

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professor

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Endocrinology and Metabolism

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available