Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

comparison of the effect of insulin glargine on glycemic control when combined with either metformin or acarbose in Type 2 diabetic patients

Protocol summary

Summary

Abstract Purpose: the analysis of the impact of insulin glargine and acarbose compared to insulin glargine and metformin in patients with type II diabetes Design: randomized clinical trial, double-blind, placebo-controlled loading, single-center Procedure: 152 patients with diabetes are divided to four groups with balanced dynamic randomization where each group contains 38 individuals. The first group (group A) uses placebo metformin and placebo Acarbose. The second group (group B) takes 500-mgl metformin pills every night; the drug dose increases for 2 grams every week, and they also use placebo Acarbose. The third group (group C) use 100 mg of Acarbose pill. The dose in the first week is 50 and then 100 mg for each meal (utmost daily doze is 300 mg); they also use metformin placebo. The fourth group (group D) uses metformin and Acarbose pill. Diet and sport is prescribed for all of the groups. Their blood is analyzed and they are clinically examined. A questionnaire is also distributed among them. Participants: Diabetes patients who refer to clinic (criteria for inclusion: type II diabetes, age range of 18-75, exclusion criteria: suffering from chronic diseases, the consumption of insulin) Interference: The prescription of Acarbose, Metformin prescription Major outcome: Fasting blood glucose, blood sugar two hours after breakfast, glycosylated hemoglobin, creatinine, triglycerides, cholesterol, high density lipoprotein, alanine aminotransferase, aspartate aminotransferase

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201403041774N6**
Registration date: **2014-12-07, 1393/09/16**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2014-12-07, 1393/09/16

Registrant information

Name
Mojgan Sanjari
Name of organization / entity
Kerman University of Medical Science
Country
Iran (Islamic Republic of)
Phone
+98 34 1322 2506
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msanjari@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Kerman University of Medical Sciences; Exir Pharmaceutical Company;fareer asa teb Pharmaceutical Company

Expected recruitment start date

2014-08-02, 1393/05/11

Expected recruitment end date

2016-01-31, 1394/11/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison of the effect of insulin glargine on glycemic control when combined with either metformin or acarbose in Type 2 diabetic patients

Public title

Insulin glargine and acarbose in the treatment of type II

diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1. Type 2 diabetes (based on American Diabetes Association criteria) 2. age group 18-75 years 3. Enough acuity and alertness to injection of insulin 4. no glycemic control with oral medications Exclusion criteria: 1. Chronic Complications of Diabetes 2. Pregnancy 3. Breastfeeding 4. Liver Disease 5. kidney disease 6. neurological disease 7. chronic inflammatory disease

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **152**

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

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

Street address

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

City

kerman

Postal code

Approval date

2013-12-04, 1392/09/13

Ethics committee reference number

K.92.318

Health conditions studied

1

Description of health condition studied

Diabet mellitus

ICD-10 code

E11

ICD-10 code description

non insulin dependent diabetes mellitus

Primary outcomes

1

Description

Plasma glucose

Timepoint

During of study

Method of measurement

Blood sample

2

Description

HbA1c

Timepoint

0, 90

Method of measurement

Blood sample

3

Description

Hypoglycemia

Timepoint

Self - monitoring of blood glucose

Method of measurement

Questionnaire and blood tests during raid

Secondary outcomes

1

Description

Laboratory Tests

Timepoint

Before and one month, two months, three months after the intervention

Method of measurement

blood and urine sample

2

Description

Weight and blood prussre and others

Timepoint

Before and one month, two months, three months after the intervention

Method of measurement

Barometer system and standard weight

Intervention groups

1

Description
The first group (group A) uses placebo metformin and placebo Acarbose
Category
Placebo

2

Description
The second group (group B) takes 500-mgl metformin pills every night; the drug dose increases for 2 grams every week, and they also use placebo Acarbose.
Category
Placebo

3

Description
The third group (group C) use 100 mg of Acarbose pill. The dose in the first week is 50 and then 100 mg for each meal (utmost daily doze is 300 mg); they also use metformin placebo.
Category
Placebo

4

Description
The fourth group (group D) uses metformin and Acarbose pill.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Kerman Afzalipour Hospital
Full name of responsible person
Mehrnaz soltani nejad
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AfzaliPour Hospital, Adjacent to Bahonar University, AfzaliPour Landscape, Imam highway, Kerman
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Physiology research center, Vice chancellor for Research and Technology of kerman medical University
Full name of responsible person
Dr.Hamid Najafi pour
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Physiology research center, Vice chancellor for Research and Technology of University of Medical Sciences, In front of Besat clinic, the begining of Ebn-e-Sina street, the begining of Jahad Boulevard, Tahmasb Abad crossroads, Kerman
City
Kerman
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Physiology research center, Vice chancellor for Research and Technology of 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
Associated professor

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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