

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 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-mg 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

Email address

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 beginning of Ebn-e-Sina street, the beginning 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-mg 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

Street address

AfzaliPour Hospital, Adjacent to Bahonar University, AfzaliPour Landscape, Imam highway, Kerman

City

kerman

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

Street address

Physiology research center, Vice chancellor for Research and Technology of University of Medical Sciences, In front of Besat clinic, the beginning of Ebn-e-Sina street, the beginning 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

Full name of responsible person

Dr. Mojgan Sanjari

Position

Kerman Afzalipour Hospital

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

AfzaliPour Hospital, Adjacent to Bahonar University,
AfzaliPour Landscape, Imam highway, Kerman

City

kerman

Postal code

7616913911

Phone

+98 34 1322 2250

Fax

+98 34 1211 3426

Email

msanjari@kmu.ac.ir

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

Kerman Afzalipour Hospital

Full name of responsible person

Dr. Mojgan Sanjari

Position

Associated professor

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

AfzaliPour Hospital, Adjacent to Bahonar University,
AfzaliPour Landscape, Imam highway, Kerman

City

Kerman

Postal code

7616913911

Phone

+98 34 1322 2250

Fax

+98 34 1322 2763

Email

msanjari@kmu.ac.ir

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

Kerman Afzalipour Hospital

Full name of responsible person

Dr. Mojgan Sanjari

Position

Associated Professor

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

AfzaliPour Hospital, Adjacent to Bahonar University,
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City

Kerman

Postal code

7616913911

Phone

+98 34 1322 2250

Fax

+98 34 1322 2763

Email

msanjari@kmu.ac.ir

Web page address

<http://www.kmu.ac.ir/sitewizard/admin/wizard/Default.aspx?Pageld=3089>

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