

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Evaluating the Effect of Cabergoline on insulin resistance and anthropometric parameters in patients with Impaired fasting glucose and/or Impaired glucose tolerance, a randomized, blinded clinical trial.

Protocol summary

Study aim

The effect of cabergoline on insulin resistance in patients with IGT using HOMA-IR model and comparison with placebo

Design

A randomized, blinded and parallel groups trial. Randomization was done with simple randomization method

Settings and conduct

The recruitment of patients will be done in Ayatollah Taleghani Hospital, Tehran, Iran. All Participants, Investigators, Outcome assessors, Data analyst and quality controller are blinded

Participants/Inclusion and exclusion criteria

Adult Patients (20-65 years) who were diagnosed as impaired fasting glucose and/or impaired glucose tolerance were included in this study, who had a history of severe hepatic failure (Child-Pugh scores of 10 or higher), history of pulmonary, pericardial, cardiac valvular, or retroperitoneal fibrotic disorders, history of hypersensitivity reaction to ergot derivatives, those with uncontrolled hypertension, diagnosed diabetes, major psychiatric disorders, bulimia or/and anorexia nervosa, pregnant or nursing mothers and those who are receiving medications which affect prolactin secretion, were excluded from this study.

Intervention groups

Test Group: 15 tablets of cabergoline 0.5 mg Placebo Group: 15 tablets of placebo with similar shape and color

Main outcome variables

The main outcomes of the study is fasting plasma glucose, 2h plasma glucose, Hb A1c, 2h insulin, weight, wrist circumference and body mass index.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170608034390N6**
Registration date: **2020-05-06, 1399/02/17**
Registration timing: **retrospective**

Last update: **2020-05-06, 1399/02/17**

Update count: **0**

Registration date

2020-05-06, 1399/02/17

Registrant information

Name

Hadi Esmaily

Name of organization / entity

SBMU

Country

Iran (Islamic Republic of)

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+98 21 8887 3704

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-05-04, 1395/02/15

Expected recruitment end date

2019-01-05, 1397/10/15

Actual recruitment start date

2016-06-09, 1395/03/20

Actual recruitment end date

2020-01-30, 1398/11/10

Trial completion date

2020-04-17, 1399/01/29

Scientific title

Evaluating the Effect of Cabergoline on insulin resistance and anthropometric parameters in patients with Impaired fasting glucose and/or Impaired glucose tolerance, a randomized, blinded clinical trial.

Public title

Effect of Cabergoline on biochemical and anthropometric parameters of patients with prediabetes.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with Impaired Fasting Glucose and/or Impaired Glucose Tolerance Adults (18-65 years)

Exclusion criteria:

Severe hepatic failure (Child-Pugh scores of 10 or higher)
History of pulmonary, pericardial, cardiac valvular, or retroperitoneal fibrotic disorders
Hypersensitivity to ergot derivatives
Uncontrolled hypertension
Diabetes
Pregnant Women
Lactating Women
Major psychiatric disorders
Patients who are receiving medications which affect prolactin secretion
Bulimia or/and anorexia nervosa

Age

From **20 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **98**

Actual sample size reached: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Balanced block randomization

Blinding (investigator's opinion)

Triple blinded

Blinding description

In this study participants, healthcare providers, investigator, outcome assessors and data analyst and quality controller are blinded

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee in Research Institute of Endocrine Sciences and Metabolism, Shahid Beheshti Univers

Street address

Endocrinology and Metabolism Research Institute, No. 24, At the beginning of Parvaneh St., Yemen St., Velenjak St., Shahid Chamran Highway, Tehran, Iran

City

Tehran

Province

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Postal code

1467664961

Approval date

2013-10-15, 1392/07/23

Ethics committee reference number

24ECRIES92/07/23

Health conditions studied**1****Description of health condition studied**

Impaired Glucose Tolerance/Impaired Fasting Glucos

ICD-10 code

R73.02

ICD-10 code description

Impaired glucose tolerance (oral)

Primary outcomes**1****Description**

Fasting Plasma Glucose

Timepoint

Before participation, 4 weeks later and 8 weeks later

Method of measurement

Autoanalyzer

2**Description**

2h plasma glucose

Timepoint

Before participation, 4 weeks later and 8 weeks later

Method of measurement

اتوانالایزر

3**Description**

Hb A1c

Timepoint

Before participation, 4 weeks later and 8 weeks later

Method of measurement

HPLC

4

Description

2h Insulin

Timepoint

Before participation, 4 weeks later and 8 weeks later

Method of measurement

الانزرا

5

Description

Wheight

Timepoint

Before participation, 4 weeks later and 8 weeks later

Method of measurement

Scale

6

Description

Height

Timepoint

Before participation, 4 weeks later and 8 weeks later

Method of measurement

Standard Meter

7

Description

wrist circumference

Timepoint

Before participation, 4 weeks later and 8 weeks later

Method of measurement

Standard Meter

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: cabergoline 0.5 mg tablets twice weekly

Category

Treatment - Drugs

2

Description

Control group: cabergoline 0.5 mg placebo tablets twice weekly

Category

Placebo

Recruitment centers

1

Recruitment center**Name of recruitment center**

Ayatolah Taleghani Hospital

Full name of responsible person

Dr. Hadi Esmaily

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School of pharmacy, Shahid Beheshti University of Medical Sciences

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

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Shahid Beheshti university of medical sciences, taleghani hospital, shahid arabi st, yemen ave, shahid chairman highway

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Private

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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Hadi Esmaily

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Medical Pharmacy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The whole potential data is unpublished after being unidentifiable.

When the data will become available and for how long

Start the access period 6 month after pricing the result

To whom data/document is available

Researchers working in academic and industrial institutions.

Under which criteria data/document could be used

It can be used to carry out research work.

From where data/document is obtainable

Dr Hadi Esmaily, School of pharmacy, shahid beheshti university of medical sciences

What processes are involved for a request to access data/document

Sending request is available.

Comments

Sending request is available.