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 Ayatolah 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

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Iran (Islamic Republic of)

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+98 21 8887 3704

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esmaily_hadi@sbmu.ac.ir

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
Tehran
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
اتوآنالایزر

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
الایزا

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
Street address
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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Person responsible for updating data

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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.