Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Jul 2026

Evaluating the effect of Cabergoline on blood glucose control in type 2 diabetics under treatment with Metformin

Protocol summary

Study aim
Determine the effect of Cabergoline on blood glucose control in type 2 diabetic patients under treatment with Metformin

Design
The patients are divided randomly in two intervention and placebo groups via online software located at www.stat.ubc.ca/Nrollin/stats/ssize/b2.html.

Settings and conduct
Initially, all selected patients will be examined generally and their blood pressure will be controlled. In addition, general characteristics such as age, height, weight as well as initial tests including FBS, 2hPP, HbA1c, Chol-T, TG, HDL, ALT, AST, ... (B-HCG test for women of reproductive age) will be taken. The intervention group will take Cabergolin (produced by Iran hormone company), 0.25 mg twice a week during first 2 weeks and they will take Cabercolin 0.5 mg twice a week for next 12 weeks. The placebo group will take placebo tablets (similar to Cabergoline tablet) through the same protocol as intervention group. After 3 months, the patients will be visited and the tests will be repeated in the same laboratory. During the study, there will be no change in the diet or physical activity of the individuals and the routine treatment will be done for both groups in addition to study intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: type 2 diabetic patient with a history of at least 3 months receiving metformin at a dose of 2 g / day; aged 30-65 years; HbA1C levels in the range of 7-8.5 Exclusion criteria: pregnancy; suffering from other diseases

Intervention groups
The intervention group will take Cabergolin (produced by Iran hormone company), 0.25 mg twice a week during first 2 weeks and they will take Cabercolin 0.5 mg twice a week for next 12 weeks. The placebo group will take placebo tablets (similar to Cabergoline tablet in similar packages) through the same protocol as intervention group.

Main outcome variables
Fast Blood Sugar; 2-hour post prandial glucose; HbA1C

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20100314003565N9**
Registration date: **2018-06-04, 1397/03/14**
Registration timing: **registered_while_recruiting**

Last update: **2018-06-04, 1397/03/14**
Update count: **0**

Registration date
2018-06-04, 1397/03/14

Registrant information

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Akbar Aliasgarzadeh

Name of organization / entity
Tabriz University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-03-21, 1397/01/01

Expected recruitment end date
2018-11-21, 1397/08/30

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluating the effect of Cabergoline on blood glucose control in type 2 diabetics under treatment with Metformin

Public title
The effect of Cabergoline on blood glucose control in type 2 diabetic patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
A type 2 diabetic patient with a history of at least 3 months receiving metformin at a dose of 2 g / day Age from 30 to 65 years HbA1C levels in the range of 7- 8.5 Obtaining Conscious Consent from all Participants involved in the Study
Exclusion criteria:
Pregnancy The presence of other diseases (cardiovascular, kidney, liver, lung, thyroid and pituitary diseases) smoking Taking herbal remedies Taking other diabetes controller drugs
Age
From **30 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
The patients are randomly divided in two intervention and placebo groups via online software presents at: www.stat.ubc.ca/Nrollin/stats/ssize/b2.html.
Blinding (investigator's opinion)
Double blinded
Blinding description
The patients have no knowledge of the type of the drug (Cabergolin or placebo). The elevator has also no knowledge of the taken drug by patients.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tabriz University of Medical Sciences
Street address
Ethics Committee,Tabriz University of Medical Sciences, Golgasht Street
City
Tabriz
Province
East Azarbaijan
Postal code
5166614756
Approval date
2018-03-12, 1396/12/21
Ethics committee reference number
IR.TBZMED.REC.1396.1291

Health conditions studied

1

Description of health condition studied
Type 2 diabetes mellitus
ICD-10 code
E11
ICD-10 code description
Type 2 diabetes mellitus

Primary outcomes

1

Description
Fast blood sugar
Timepoint
Baseline and 3 months after the treatment
Method of measurement
Blood Test

2

Description
2-hour postprandial blood sugar
Timepoint
Baseline and 3 months after the treatment
Method of measurement
Blood Test

3

Description
HbA1C
Timepoint
Baseline and 3 months after the treatment
Method of measurement
Blood Test

Secondary outcomes

1

Description
Cholestrol
Timepoint
Basline and 3 months after the treatment
Method of measurement
Blood Test

2

Description
TG
Timepoint
Basline and 3 months after the treatment
Method of measurement
Blood Test

Intervention groups

1

Description
The intervention group will take Cabergolin (produced by Iran hormone company), 0.25 mg twice a week during first 2 weeks and they will take Cabercolin 0.5 mg twice a week for next 12 weeks.
Category
Treatment - Drugs

2

Description
Control group: The placebo group will take placebo tablets (similar to cabergoline tablets in similar packages) through the same protocol as intervention group .
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Tabriz Imam Reza Hospital
Full name of responsible person
Dr. Alireza Hadi
Street address
Department of Endocrinology, Imam Reza Hospital, Daneshgah Square, Tabriz, East Azarbaijan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr. Abolghasem Jouyban
Street address
Vice chancellor for Research,Tabriz University of Medical Sciences, Golgasht Street, Tabriz
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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
Tabriz University of Medical Sciences
Proportion provided by this source
100
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
Tabriz University of Medical Sciences
Full name of responsible person
Dr. Akbar Aliasgharzadeh
Position
Professor
Latest degree
Subspecialist
Other areas of specialty/work
Endocrinology and Metabolism
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Position
Professor

Latest degree
Subspecialist

Other areas of specialty/work
Endocrinology and Metabolism

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Person responsible for updating data

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Latest degree
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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
No - There is not a plan to make this available

Clinical Study Report
Yes - There is 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

Title and more details about the data/document
The total potential data can be shared after making patiens' data unidentifiable

When the data will become available and for how long
The access period Starts 3 months after publishing the results

To whom data/document is available
All medical doctors and scientific researchers

Under which criteria data/document could be used
merely for other medical studies

From where data/document is obtainable
Dr. Alireza Hadi, Tel: 00989142175242, Email: Dr.alirezahadi46@gmail.com

What processes are involved for a request to access data/document
Initially, the data will be asked by e-mail. If the email is not answered within 10 days, the data should be asked by phone.

Comments