Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 2026

The efficacy of bromocriptine for glycemic control in poorly controlled type 2 diabetic patients

Protocol summary

Summary

Type 2 diabetes patients who are uncontrolled (HbA1C between 7.5% and 9%), in spite of maximum dose of metformin and glibenclamide, are entered into the study after notification and their permission. First, patients' demographic characteristics (age, gender, duration disease, height, weight, abdomen circumference) are determined. Next, base lab tests including, FBS, 2HPPBS, HbA1C, Chol, Tg, HDL are obtained. We start medication with low dose of bromocriptine (1.25 milligram) in bedtime. And, 1.25 milligram of the drug will be added every 3 days (in cases of no complication). We continue this until we reach 2.5 miligram of the drug twice a day. In first visit (1.5 month after starting), FBS, 2HPPBS will be measured. In second and third visit (3 months and 6 months), weight, FBS, 2HPPBS, HbA1C, Chol, Tg, HDL will be evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201204156710N3**
Registration date: **2012-05-28, 1391/03/08**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-05-28, 1391/03/08

Registrant information

Name
Mitra Niafar
Name of organization / entity
Tabriz university of medical sciences
Country
Iran (Islamic Republic of)
Phone
+98 41 1335 7850
Email address
niafarm@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Tabriz University of medical sciences

Expected recruitment start date

2012-05-04, 1391/02/15

Expected recruitment end date

2012-09-05, 1391/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The efficacy of bromocriptine for glycemic control in poorly controlled type 2 diabetic patients

Public title

Effect of bromocriptine in diabetes treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: All type 2 diabetes patients who do not have exclusion criteria. Exclusion criteria: 1- Age lower than 30 and more than 65; 2- HbA1C lower than 7.5% and more than 9%; 3- Patients who are not willing to participate; 4- Pregnant patients and lactating patients; 5- Syncope attacks; 6- Severe psychosis; 7- Sensitive to bromocriptine and ergot drugs.

Age

From **30 years** old to **65 years** old

Gender

Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Vice chancellor for research of Tabriz university of medical sciences
Street address
Tabriz university of medical sciences, Golgasht street
City
Tabriz
Postal code
Approval date
2012-03-12, 1390/12/22
Ethics committee reference number
917

Health conditions studied

1

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

Primary outcomes

1

Description
Blood sugar
Timepoint
1.5 months
Method of measurement
lab tests

Secondary outcomes

1

Description
Lipid profile
Timepoint
3 and 6 months
Method of measurement
lab tests

Intervention groups

1

Description
We start medication with low dose of bromocriptine (1.25 milligram) in bedtime. And, 1.25 milligram of the drug will be added every 3 days (in cases of no complication). We continue this until we reach 2.5 miligram of the drug twice a day.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Specialized clinic of Tabriz University of medical sciences
Full name of responsible person
Nooshin Milanchan
Street address
Imam Reza and Sina medical centers
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research of Tabriz University of medical sciences
Full name of responsible person
Alireza Ostadrahimi
Street address
Tabriz University of Medical sciences, Danshgah street, Goldasht Ave
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research of Tabriz University of

medical sciences

Proportion provided by this source
100

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
Medical faculty of Tabriz University of medical sciences

Full name of responsible person
Dr. Nooshin Milanchian

Position
Endocrinology and Metabolism Fellow

Other areas of specialty/work

Street address
Imam Reza hospital, endocrine center

City
Tabriz

Postal code

Phone
+98 41 1335 7850

Fax

Email
noomilan@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Medicine faculty, Tabriz University of medical sciences

Full name of responsible person
Dr. Nooshin Milanchian

Position
Endocrinology and Metabolism Fellow

Other areas of specialty/work

Street address
Imam Reza hospital, endocrine center

City
Tabriz

Postal code

Phone
+98 41 1335 7850

Fax

Email
noomilan@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Medical faculty of Tabriz University of medical sciences

Full name of responsible person
Nooshin Milanchian

Position
Endocrinology and Metabolism Fellow

Other areas of specialty/work

Street address
Imam Reza hospital, endocrine center

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Phone
+98 41 1335 7850

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Email
noomilan@yahoo.com

Web page address

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