

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 milligram 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, Danshghah 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

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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

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Other areas of specialty/work

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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

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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