

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Comparing the effectiveness and side effects of Venlafaxine and Bupropione in diabetic patients with depression

Protocol summary

Study aim

Evaluation the effectiveness, safety and side effects of Venlafaxine and Bupropione in adult diabetic patients with depression

Design

This randomized clinical trial with control group will be conducted on 60 adult diabetic patients with depression. These patients will be allocated randomly in two groups; intervention group (with Venlafaxine) and control group (with Bupropione).

Settings and conduct

This randomized clinical trial will be implemented in the clinic of endocrinology affiliated to Babol University of Medical Sciences

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18 years and over; The presence of depressive symptoms in psychiatric clinical interview; Confirmation of type 2 diabetes mellitus based on diagnosis of research's endocrinologist. Exclusion criteria: Pregnancy and breast feeding; Previous history of elevated mood, serious suicidal ideation and dementia

Intervention groups

Intervention group: Venlafaxine manufactured by Abidi's Pharmaceutical Company 75-150 milligram per day for 12 weeks. Control group: Bupropione manufactured in Abidi's Pharmaceutical Company, 150-300 milligram per day for 12 weeks

Main outcome variables

Depressive symptoms; The patients' blood glucose

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150630022991N12**

Registration date: **2018-08-15, 1397/05/24**

Registration timing: **registered_while_recruiting**

Last update: **2018-08-15, 1397/05/24**

Update count: **0**

Registration date

2018-08-15, 1397/05/24

Registrant information

Name

Sussan Moudi

Name of organization / entity

Babol University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-06, 1397/05/15

Expected recruitment end date

2019-02-04, 1397/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effectiveness and side effects of Venlafaxine and Bupropione in diabetic patients with depression

Public title

Venlafaxine and Bupropione in diabetic patients with depression

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 years and over The presence of depressive symptoms in psychiatric clinical interview Confirmation of type 2 diabetes mellitus based on the diagnosis of research's endocrinologist

Exclusion criteria:

Pregnancy and breast feeding Previous history of high mood, serious suicidal ideation and dementia

Age

From 18 years old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Simple random allocation with random numbers table

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Babol University of Medical Sciences

Street address

Ganjafrooz Avenue, Babol

City

Babol

Province

Mazandaran

Postal code

4136747176

Approval date

2018-07-08, 1397/04/17

Ethics committee reference number

IR.MUBABOL.HRI.REC.1397.094

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

Depressive symptoms

Timepoint

At baseline and at the end of the 12th week after intervention

Method of measurement

Beck Depression Inventory

2

Description

Blood glucose

Timepoint

At baseline and at the end of the 12th week after intervention

Method of measurement

Fasting blood glucose; 2 hours post-prandial blood glucose and hemoglobin A1C

Secondary outcomes

1

Description

Drug side effects

Timepoint

At baseline and at the end of the 12th week after intervention

Method of measurement

Medical visit

Intervention groups

1

Description

Intervention group: Venlafaxine manufactured by Abidi's Pharmaceutical Company 75 -150 milligram per day for 12 weeks

Category

Treatment - Drugs

2

Description

Control group: Bupropione manufactured by Abidi's Pharmaceutical Company 150 -300 milligram per day for 12 weeks

Category

Recruitment centers**1****Recruitment center****Name of recruitment center**

Ayatollah Rouhani Hospital

Full name of responsible person

Sussan Moudi, MD

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Ayatollah Rouhani Hospital, Ganjafrroz avenue, Babol

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Babol University of Medical Sciences

Full name of responsible person

Reza Ghadimi, PhD

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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

Babol 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**Person responsible for general inquiries****Contact****Name of organization / entity**

Babol University of Medical Sciences

Full name of responsible person

Sussan Moudi, MD

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

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

Not applicable

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

The data associated with the study can be shared potentially when the study population are unidentifiable.

When the data will become available and for how long

After publication of the final project report

To whom data/document is available

Researchers in universities and academic organizations

Under which criteria data/document could be used

In order to use the study results in future researches

From where data/document is obtainable

Sending an email to Dr. Sussan Moudi with email address
sussan.mouodi@gmail.com

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

Within a maximum time of one month after receipt of the request, it will be answered.

Comments