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

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Iran (Islamic Republic of)

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+98 11 3236 5683

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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

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Ayatollah Rouhani Hospital
Full name of responsible person
Sussan Moudi, MD
Street address
Ayatollah Rouhani Hospital, Ganjafrooz avenue, Babol
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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

Type of organization providing the funding
Academic

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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Person responsible for updating data

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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