Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jul 2026

Comparison of the Effectiveness of Sertraline and Fluoxetin in Diabetic Patients with Depression

Protocol summary

Study aim
Comparison of the Effectiveness of Sertraline and Fluoxetine in Diabetic Patients with Depression
Design
Randomised controlled parallel group trial
Settings and conduct
Forty adult patients (18 years and above) with clinical diagnosis of diabetes type 2 referring to the endocrinology clinic affiliated to Babol University of Medical Sciences who have been diagnosed as depressive disorder in a clinical psychiatric interview will be allocated randomly in the two case and control groups.
Participants/Inclusion and exclusion criteria
Inclusion Criteria: Age 18 years and above; Depressive symptoms in a clinical psychiatric interview; Confirmation of diabetes type 2 diagnosed by an endocrinologist Exclusion Criteria: Pregnancy or lactation; Probability to migrate from the city in duration time of the study; Comorbidity of uncontrolled cardiovascular or ophthalmic diseases
Intervention groups
Intervention Group: Sertraline 50-200 milligram per day for 12 weeks Control Group: Fluoxetin 20-60 milligram per day for 12 weeks
Main outcome variables
The status of blood glucose in the patients

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20150630022991N9**
Registration date: **2018-03-10, 1396/12/19**
Registration timing: **retrospective**

Last update: **2018-03-10, 1396/12/19**
Update count: **0**
Registration date
2018-03-10, 1396/12/19

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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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2017-09-06, 1396/06/15
Expected recruitment end date
2017-10-22, 1396/07/30
Actual recruitment start date
2017-09-06, 1396/06/15
Actual recruitment end date
2017-10-22, 1396/07/30
Trial completion date
empty

Scientific title
Comparison of the Effectiveness of Sertraline and Fluoxetin in Diabetic Patients with Depression

Public title
Sertraline and Fluoxetin in Diabetic Patients with Depression
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:

Age 18 years and above The presence of depressive symptoms in a clinical psychiatric interview The confirmation of diabetes type 2 diagnosed by an endocrinologist To provide the informed consent form

Exclusion criteria:

Pregnancy or lactation Probability to migrate from the city in duration time of the study Comorbidity of uncontrolled cardiovascular or ophthalmic diseases

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Actual sample size reached: **40**

Randomization (investigator's opinion)

Not randomized

Randomization description

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

City

Babol

Province

Mazandaran

Postal code

4136747176

Approval date

2017-06-18, 1396/03/28

Ethics committee reference number

MUBABOL.REC.1396.16

Health conditions studied

1

Description of health condition studied

Diabetes Mellitus

ICD-10 code

E08

ICD-10 code description

Diabetes mellitus due to underlying condition

Primary outcomes

1

Description

Blood Glucose

Timepoint

Baseline and three months after intervention

Method of measurement

Assessment of fasting blood glucose, 2 hours post prandial blood glucose and HbA1C

Secondary outcomes

1

Description

Serum lipid profile

Timepoint

Baseline and three months after intervention

Method of measurement

To test serum triglyceride, cholesterol, HDL and LDL

2

Description

The severity of depression

Timepoint

Baseline and three months after intervention

Method of measurement

Beck Depression Scale

Intervention groups

1

Description

Intervention group: 50-200 milligram per day sertraline manufactured in Doctor Abidi Pharmacy Company

Category

Treatment - Drugs

2

Description

Control group: 20-60 milligram per day fluoxetin 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
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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
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Full name of responsible person
Sussan Moudi, MD
Position
Psychiatrist
Latest degree
Specialist
Other areas of specialty/work
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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
Yes - There is a plan to make this available

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
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Information related to primary and secondary outcomes will be reported in the results part of the manuscript.

When the data will become available and for how long
It will be determined after publication of the manuscript.

To whom data/document is available
All of researchers

Under which criteria data/document could be used
In order to exploit the results of the research for future studies

From where data/document is obtainable
Email address of Doctor Sussan Moudi: sussan.mouodi@gmail.com

What processes are involved for a request to access data/document
The request will be sent after a maximum of 10 days following receipt of the email.

Comments