

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the Effectiveness of Sertraline and Fluoxetine 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: Fluoxetine 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

Country

Iran (Islamic Republic of)

Phone

+98 11 3236 5683

Email address

sussan.mouodi@mubabol.ac.ir

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 Fluoxetine in Diabetic Patients with Depression

Public title

Sertraline and Fluoxetine 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 fluoxetine 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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4718747415

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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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alibijani@yahoo.com

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

Psychiatrist

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

Street address

Shahid Yahyanejad Hospital, Department of Psychiatry

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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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