Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Sertraline effectiveness in prevention of depression, fatigue reduction and QOL improvement in MS patients.

Protocol summary

Summary

1) Objectives: Sertraline effectiveness in prevention of depression, fatigue reduction and QOL improvement in MS patients. 2) Design: Double- blinded,randomized clinical trails. 3)Setting and conduct : The patients with multiple sclerosis from neurology clinic of Razi hospital were referred to our study by neurologist will be divided into two groups,intervention and control . 4)Participants: The patients with multiple sclerosis from neurology clinic of Razi hospital with inclusion criteria(Age 15-60;Primary education) and exclusion criteria(Other Organic illnesses:Other mental disorder;Smoking and substance induce or alcohol abuser) were referred to our study by neurologist . 5)Intervention : Sertralin 50 mg daily in intervention group and placebo daily in control group . 6) Main outcomes measurement variables:Depression, Fatigue, Quality Of Life .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015090723927N1**
Registration date: **2015-11-02, 1394/08/11**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-11-02, 1394/08/11

Registrant information

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Mohammad Askarpour
Name of organization / entity
Tabriz university of medical science
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research,Tabriz university of medical science.

Expected recruitment start date

2015-09-21, 1394/06/30

Expected recruitment end date

2016-03-19, 1394/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Sertraline effectiveness in prevention of depression, fatigue reduction and QOL improvement in MS patients.

Public title

Sertraline effectiveness in prevention of depression in MS patients.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion Criteria: Age 15-60;Primary education
Exclusion; Other Organic illnesses:Other mental disorder;Smoking and substance induce or alcohol abuser.

Age

From **79 years** old to **34 years** old

Gender

Both

Phase

2-3
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

1

Registry name

Secondary trial Id

Registration date
empty

2

Registry name

Secondary trial Id

Registration date
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tabriz university of medical sciences
Street address
Flour 3, Building 2, Golgasht Av, Tabriz university of medical science
City
Tabriz
Postal code
Approval date
2015-09-02, 1394/06/11
Ethics committee reference number
TBZMED.REC.1394.493

Health conditions studied

1

Description of health condition studied
Multiple sclerosis
ICD-10 code
G35
ICD-10 code description
Multiple sclerosis

Primary outcomes

1

Description
Depresion
Timepoint
Atfirst of study, 1 mth later, 3mth later, 6 mth later
Method of measurement
Hamilton Questionnaire

2

Description
Decreament OF Fatigue
Timepoint
Atfirst of study, 1 mth later, 3mth later, 6 mth later
Method of measurement
SF_36 Questionnaire

3

Description
Quality of life
Timepoint
Atfirst of study, 1 mth later, 3mth later, 6 mth later
Method of measurement
FSS Questionnaire OF QOL

Secondary outcomes

1

Description
Probably switch to mania.
Timepoint
During fallow up times.
Method of measurement
Based on DSM criteria.

Intervention groups

1

Description
In study group we will add 50 mg sertraline produced by sobhan manufacture every day for six months,this group will consider at the beginning ,end of 1th month, 3th month and end 6th month for depression symptoms.
Category
Prevention

2

Description
In control group we will add one placebo produced by pharmacy faculty of Tabriz university of medical science

for six months every day . They will consider at the beginning , end of 1th month ,3th month and end of 6th month.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Razi Hospital

Full name of responsible person
Dr Shaafi(Associate professor)Dr Hashemilar(Associate professor)

Street address
Neurology ward, RAzi hospital Eal Goli ave Tabriz.

City
Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research,Tabriz university of medical science.

Full name of responsible person
Hassan Soleimanpour

Street address
Tabriz university of medical science,Golgasht Ave,Tabriz,Iran

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,Tabriz university of medical science.

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
Tabriz university of medical science

Full name of responsible person
Mohammad Askarpour

Position
Resident

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz University Of Medical Scienve

Full name of responsible person
Sepideh Herizchi Ghadim

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Psychiatrist

Other areas of specialty/work

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Person responsible for updating data

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Resident

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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