

# 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 trials. 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

###### Name

Mohammad Askarpour

###### Name of organization / entity

Tabriz university of medical science

###### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3660 7265

##### Email address

askarpour@tbzmed.ac.ir

##### 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**

**Street address**

Tabriz university of medical science, Golgasht Av, Tabriz, Iran

**City**

Tabriz

**Postal code**

**Phone**

+98 41 3336 4667

**Fax**

**Email**

info@medfac.tbzmed.ac.ir

**Web page address**

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Tabriz University Of Medical Science

**Full name of responsible person**

Sepideh Herizchi Ghadim

**Position**

Psychiatrist

**Other areas of specialty/work**

**Street address**

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

**City**

Tabriz

**Postal code**

**Phone**

+98 41 3335 5921

**Fax**

**Email**

http://mail.tbzmed.ac.ir/

**Web page address**

www.tbzmed.ac.ir

## Person responsible for updating data

#### Contact

**Name of organization / entity**

Tabriz University Of Medical Science

**Full name of responsible person**

Mohammad Askarpour

**Position**

Resident

**Other areas of specialty/work**

**Street address**

Razi Hospit ,Eal Goli Ave, Tabriz , Iran

**City**

Tabriz

**Postal code**

**Phone**

+98 41 3660 7265

**Fax**

**Email**

askarpour@tbzmed.ac.ir; md.askarpour@gmail .com

**Web page address**

*empty*

## **Sharing plan**

**Informed Consent Form**

*empty*

**Deidentified Individual Participant Data Set (IPD)**

**Clinical Study Report**

*empty*

*empty*

**Study Protocol**

**Analytic Code**

*empty*

*empty*

**Data Dictionary**

**Statistical Analysis Plan**

*empty*