

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jun 2026

A study of sertraline effect on quality of life in stroke inpatients

Protocol summary

Summary

Evaluation of preventive effects of sertraline in reducing physical and mental disabilities of patients with stroke of brain and increasing their therapeutic alliance and quality of life. 80 patients admitted to neurology ward of Razi university hospital during 2012-2013 will be enrolled in this study and will be randomly assigned to two groups receiving either sertraline or placebo. patients from both gender aged between 55 and 75 which are experiencing stroke for the first time will be enrolled. Patients with renal, hepatic or cardiac failure and patients with substance related disorders will be excluded. The two groups will be monitored every 3 months regarding recurrent stroke, therapeutic alliance, procedure of the therapy and degree of disability for 9 months according to the questionnaires of Quality of life and Beck Depression Inventory.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012101011062N1**

Registration date: **2012-11-28, 1391/09/08**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-11-28, 1391/09/08

Registrant information

Name

Reza Pirzeh

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1380 3353

Email address

pirzehr@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2012-09-10, 1391/06/20

Expected recruitment end date

2012-12-10, 1391/09/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A study of sertraline effect on quality of life in stroke inpatients

Public title

sertraline effect on stroke

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: inpatients which are experiencing stroke for the first time will be enrolled. Exclusion criteria: past history of stroke ;renal failure; hepatic failure; cardiac failure; substance related disorders

Age

From **55 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Triple blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Tabriz University of Medical Sciences (TUOMS)

Street address

Univesity Main Street, Tabriz, Iran tel :3355921

City

tabriz

Postal code

5165687386

Approval date

2012-03-12, 1390/12/22

Ethics committee reference number

9091

Health conditions studied**1****Description of health condition studied**

Stroke

ICD-10 code

I64

ICD-10 code description

Stroke, not specified as haemorrhage or infarction

Primary outcomes**1****Description**

Quality of life

Timepoint

3 months, 6 months, 9 months

Method of measurement

Nottingham Health Profile

Secondary outcomes**1****Description**

Depression

Timepoint

3 months, 6 months, 9 months

Method of measurement

Beck depression inventory

Intervention groups**1****Description**

Intervention:3 weeks after stroke each patient in this group reseived Sertraline 50 mg per day for 12 months.

Category

Treatment - Drugs

2**Description**

control: 3 weeks after stroke each patient in this group reseived a placebo tablet every day.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Razi Hospital

Full name of responsible person

Reza Pirzeh

Street address

Psychiatry department, Razi Hospital, El Goli Road, tabriz,East AZerbaijan, Iran

City

Tabriz

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tabriz University of medical sciences, Vice chancellor of research

Full name of responsible person

Ali Meshkini M.D

Street address

Dean of Research, Faculty of Medicine, Tabriz University of Medical Sciences, Univesity Main Street, 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

Tabriz University of medical sciences, Vice chancellor of

research

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

Department of Psychiatry

Full name of responsible person

Reza Pirzeh

Position

Resident in psychiatry

Other areas of specialty/work

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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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz Univeristy of medical sciences

Full name of responsible person

Mohammad Ali Ghoreishizadeh

Position

Professor

Other areas of specialty/work

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