Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 stoke 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 Siences
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Iran (Islamic Republic of)
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+98 41 1380 3353
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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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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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Person responsible for updating data

Contact

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Full name of responsible person

Raze Pirzeh

Position

Resident in psychiatry

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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