

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Effect of fluoxetine on functional recovery of patients with cerebrovascular accident following middle cerebral artery trunk obstruction: a randomized clinical trial

Protocol summary

Summary

The aim of this study is to evaluate the effect of fluoxetine on functional recovery of patients with ischemic stroke. The present study is a double blind randomized clinical trial. Patients with ischemic stroke due to occlusion of middle cerebral artery trunk will be enrolled base on inclusion criteria. Written informed consent will be obtained from all patients or their families before their inclusion in the study. Participates will be assigned into two groups randomly, using random block, receiving 15 mg fluoxetine or placebo for the first month starting 24 hours after the onset of stroke and then 20 mg for the next two months. Patient will be excluded if any adverse effect happens due to medication. Functional recovery of patients will be evaluated by National Institute of Health Stroke Scale Criteria (NIHSS) and the Beck Depression Inventory (BDI) at the time of admission, date of discharge and 1 month and 3 months and also Modified Rankin Scale (MRS) and Barthel Index (BI) in discharge, 1 month and 3 months after drug administration.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201112228490N1**
Registration date: **2012-01-25, 1390/11/05**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2012-01-25, 1390/11/05

Registrant information

Name

Seyed Mohammad Seyed Saadat

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

00983221572-00983223856

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research, Guilan university of medical sciences

Expected recruitment start date

2012-04-05, 1391/01/17

Expected recruitment end date

2013-04-05, 1392/01/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of fluoxetine on functional recovery of patients with cerebrovascular accident following middle cerebral artery trunk obstruction: a randomized clinical trial

Public title

Effect of fluoxetine on the functional recovery of patients with cerebrovascular accident

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: informed consent; unilateral occlusion of middle cerebral artery trunk; resident in Rasht;

Admission NIHSS < 20; No history of alcohol abuse; No history of insomnia, epilepsy; No previous history of cerebral hemorrhage and heart of cerebral stroke; No previous history of systemic diseases of other organs, including liver failure and kidney; Absence of cardiac pace maker, severe neuropathy, systemic vascular disease or major affective disorders; Absence of concomitant stroke in an area other than the stroke of the middle cerebral artery. Exclusion criteria: Dissatisfaction of patient during the study; Occurrence of serious adverse drug affects at any time during drug administration; Alcohol abuse during the study period; Occurrence of Post Stroke Depression (PSD) concomitant use of the mono amine oxidase inhibitors or serotonergic drugs such as tricyclic antidepressants and SSRI.

Age

From **55 years** old to **85 years** old

Gender

Both

Phase

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**

empty

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

Ethics committee of Guilan university of medical sciences

Street address

across Alzahra hospital, Namjoo street, Siadati street

City

Rasht

Postal code

4144665385

Approval date

2012-01-11, 1390/10/21

Ethics committee reference number

1901130503

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

Cerebral ischemic stroke

ICD-10 code

I63.3

ICD-10 code description

Cerebral infarction due to thrombosis of cerebral arteries

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

Disability

Timepoint

On admission day, on discharge day, 1 and 3 month later

Method of measurement

modified Rankin Scale (mRS)

2**Description**

Performance in basic Activities of Daily Living

Timepoint

On admission day, on discharge day, 1 and 3 month later

Method of measurement

Barthel Index

3**Description**

Functional recovery

Timepoint

On admission day, on discharge day, 1 and 3 month later

Method of measurement

National Institutes of Health Stroke Scale (NIHSS)

4**Description**

Depression

Timepoint

On admission day, on discharge day, 1 and 3 month later

Method of measurement

Beck Depression Inventory (BDI) questionnaire

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

cerebral blood flow changes of middle cerebral artery

Timepoint

On admission day, on discharge day

Method of measurement

Transcranial Doppler (TCD)

Intervention groups

1

Description

Fluoxetine, 15 milligram oral pill for the first month and 20 milligram for the next two months in control group

Category

Treatment - Drugs

2

Description

Placebo, 15 milligram oral pill for the first month and 20 milligram for the next two months in control group

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Poursina Hospital, Guilan University of Medical Sciences

Full name of responsible person

Dr Seyed Ali Roudbary, Neurologist, Assistant professor

Street address

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Guilan University of Medical Science, Vice chancellor for research and technology

Full name of responsible person

Dr Abdolrasool Sobhani

Street address

Across Alzahra hospital, Siadati street, Namjoo street

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Rasht

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Guilan University of Medical Science, Vice chancellor for research and technology

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

Guilan University of Medical Sciences

Full name of responsible person

Seyed Mohammad Seyed Saadat

Position

Medical Student

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Poorsina hospital, Guilan University of Medical Sciences

Full name of responsible person

Dr Babak Bakhshayesh Eghbali

Position

Assistant professor, Neurologist

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