Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 hospitalt, Siadati street, Namjoo street
City
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
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Other areas of specialty/work
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Poorsina hospital, Guilan Uuniversity of Medical Sciences
Full name of responsible person
Dr Babak Bakhshayesh Eghbali
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Assistant professor, Neurologist
Other areas of specialty/work
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Person responsible for updating data

Contact
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Seyed Mohammad Seyed Saadat
Position
Medical Student
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