Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the Effect of Citalopram on Three Months Functional Prognosis of Acute Ischemic Stroke Patients: A Randomized Clinical Trial

Protocol summary

Summary

The aim of this double blind randomized clinical trial is to assess efficacy of Citalopram on ischemic stroke patient's functional outcome (at least 50% improvement in the 3-month NIHSS compared to the baseline score) compared with placebo. Inclusion criterion for this research is having ischemic stroke; no previous use of citalopram and other antidepressants or neuroleptic drugs, in the last month before the onset of symptoms; not having a severe disability after stroke and depression. Exclusion criteria are as: Previous chronic disease interferes with the performance evaluation in patients; Residual weakness from previous stroke; Thrombolytic therapy; Endarterectomy and Depression. 144 patients referring to Razi university hospital diagnosed as ischemic stroke will be randomly allocated to receive either Citalopram (20mg/Daily) or placebo. The main outcome of the trial is the effect of drug on functional status after ischemic stroke. The primary outcome of this study is functional status after stroke measured through.(National Institutes of Health Stroke Scale(NIHSS) and modified Rankin scale (mRS) three times (At hospitalization, discharge and after 3 months).

General information

Acronym

COISO

IRCT registration information

IRCT registration number: **IRCT201203192150N2**
Registration date: **2012-04-22, 1391/02/03**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2012-04-22, 1391/02/03

Registrant information

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Name of organization / entity

Tabriz University of medical sciences

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Recruitment status

Recruitment complete

Funding source

Neurosciences Research center of Tabriz University of medical sciences.

Expected recruitment start date

2012-05-10, 1391/02/21

Expected recruitment end date

2012-10-10, 1391/07/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the Effect of Citalopram on Three Months Functional Prognosis of Acute Ischemic Stroke Patients: A Randomized Clinical Trial

Public title

Effect of Citalopram on Three Months Functional Prognosis of Acute Ischemic Stroke Patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1- Acute ischemic stroke hospitalization in Razi university hospital; 2- No previous use of

citalopram and other antidepressants, MAOI, Neuroleptic drugs and benzodiazepines in the last month before the onset of symptoms; 3- Not having a severe disability after stroke(NIHSS<20); 4-Not having Depression(MADRS>18). Exclusion criteria: 1- Request of patients to Exit from the study; 2- Previous chronic disease interferes with the performance evaluation in patients such as: chronic infections, liver or kidney failure, cancers; 3- Residual weakness of previous stroke; 4- Pregnancy or breastfeeding or any conditions that makes follow up impossible; 5- Sever loss of Consciousness; 6- Thrombolytic therapy; 7- Endarterectomy; 8- Depression(MADRS>18).

Age
From **18 years** old to **100 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **144**

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
Tabriz University of medical sciences

Street address
Daneshgah street , Deputy for research, Tabriz university of medical sciences

City
Tabriz

Postal code

Approval date
2012-03-05, 1390/12/15

Ethics committee reference number
9094

Health conditions studied

1

Description of health condition studied
Ischemic stroke

ICD-10 code
I63

ICD-10 code description
Cerebral infarction

Primary outcomes

1

Description
Functional status after stroke

Timepoint
At hospitalization(0), discharge(1), and after 3 months(2)

Method of measurement
Functional status score based on NIHSS(National institutes of health stroke scale)(at least 50% reduction in NIHSS score in 3-month compared to the baseline score

Secondary outcomes

1

Description
Prognosis after stroke

Timepoint
At hospitalization(0), discharge(1), and after 3 months(2)

Method of measurement
Modifi ed Rankin scale (MRS)

Intervention groups

1

Description
Citalopram tablets(produced with commercial name as Citalopram product by Sobhan Pharma Co.)/ 20 mg Daily

Category
Treatment - Drugs

2

Description
Placebo as the same shape and size and color as Citalopram tablets

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Razi University hospoital

Full name of responsible person
Dr. Savadi oskoei

Street address

City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Neurosciences Research Center
Full name of responsible person
Dr.Farhoudi
Street address
Golgasht street, Imam Reza Hospital, Neurosciences Research Center
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Neurosciences Research Center
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

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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