

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jun 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

##### Name

Homayoun Sadeghi Bazargani

##### Name of organization / entity

Tabriz University of medical sciences

##### Country

Iran (Islamic Republic of)

##### Phone

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##### Email address

homayoun.sadeghi@arums.ac.ir

#### 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**

Modified 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 hospital

**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

### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr. Ehsan Sharifipour

**Position**

MD, Resident of Neurology specialty degree

**Other areas of specialty/work**

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## Person responsible for scientific

## inquiries

### Contact

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**Full name of responsible person**

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**Position**

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## Person responsible for updating data

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**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*