

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### The efficacy comparison of fluoxetine and citalopram on motor recovery after ischemic stroke: single-blind placebo-controlled randomized clinical trial

#### Protocol summary

##### Study aim

Comparison of the efficacy of fluoxetine and citalopram on the improvement of motor function after ischemic stroke

##### Design

A randomized, randomized, phase 3 clinical trial in 90 patients was used to randomize the random function of Excel software.

##### Settings and conduct

Giving the patient matched capsules to compare the effectiveness of citalopram and fluoxetine on improving motor function after ischemic stroke, the site of intervention at Ayatollah Rouhani Hospital - a single-blind clinical trial with blind participants

##### Participants/Inclusion and exclusion criteria

The study population includes patients who are admitted to Ayatollah Rouhani Hospital with a diagnosis of ischemic stroke. Inclusion criteria include age over 18 - Hemiplegia or hemiparesis after the first ischemic stroke in the last 24 hours. Withdrawal conditions, including patients with ischemic stroke, initially lost consciousness and were admitted to the ICU. The patient has a history of psychiatric disorders. Having movement disorders before stroke, pregnancy and lactation, patients receiving psychiatric medication. Existence of any therapeutic contraindications such as renal failure (GFR) below 30 and impaired liver function tests, hyponatremia, long QT interval. Occurrence of any significant drug side effects during treatment such as restlessness, hypertension or symptoms of serotonin syndrome

##### Intervention groups

Group A, which consists of 30 people, is treated with fluoxetine, group B, which consists of 30 people, is treated with citalopram, and group C, which is the control group, is treated with placebo. In addition to the standard treatments for ischemic stroke for all three

groups.

##### Main outcome variables

Age - Gender - Blood pressure - Total dose of prescribed drug - Motor score of NIHSS motor scale

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210307050617N1**

Registration date: **2021-03-27, 1400/01/07**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-03-27, 1400/01/07**

Update count: **0**

##### Registration date

2021-03-27, 1400/01/07

##### Registrant information

##### Name

Fatemeh Karimi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3219 2034

##### Email address

karimif632@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-03-26, 1400/01/06

##### Expected recruitment end date

2021-12-22, 1400/10/01

##### Actual recruitment start date

empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
The efficacy comparison of fluoxetine and citalopram on motor recovery after ischemic stroke: single-blind placebo-controlled randomized clinical trial

**Public title**  
Comparison of the effect of fluoxetine and citalopram on motor recovery after ischemic stroke, single-blind clinical trial

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Age over 18 years Hemiparesis or hemiplegia after the first ischemic stroke in 24 hours A score greater than 2 NIHSS scale motion items  
**Exclusion criteria:**

**Age**  
From **18 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**  

- Participant

**Sample size**  
Target sample size: **90**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Balanced (permuted) block randomization with a block size of 30 people and three groups ( A,B,C ).

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
Patients in this study are blind . In this way drugs and placebo are poured into the capsule to match the same size and color, the capsules of each group are poured into cans and given to patients, and the patient is unaware of the type of drug. And the doctor knows what kind of medicine the patient has received (fluoxetine group A, citalopram group B, placebo group C ) which is recorded in the patient's demographic information question.

**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**  
empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Babol University of Medical Sciences

##### Street address

Rouhani hospital, Ganjafroz street, Babol, Mazandaran

##### City

Babol

##### Province

Mazandaran

##### Postal code

4717647745

#### Approval date

2020-08-22, 1399/06/01

#### Ethics committee reference number

IR.MUBABOL.REC.1399.279

## Health conditions studied

### 1

#### Description of health condition studied

Ischemic stroke

#### ICD-10 code

I63.9

#### ICD-10 code description

Cerebral infarction, unspecified

## Primary outcomes

### 1

#### Description

Evaluate the rate of improvement in motor function after receiving the drug after one, two and three months

#### Timepoint

The patient's motor function is measured every month. The study time on each case is 90 days

#### Method of measurement

Using the NIHSS scale motion item

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group 1: The first intervention group is group A, which has 30 patients. They are given fluoxetine capsules made by Aria Company at a dose of 20 mg daily for three months, and at the end of the first, second and third months, the rate of subsequent motor function improvement is evaluated in patients based on the NIHSS motor scale and drug side effects.

**Category**

Treatment - Drugs

**2****Description**

Intervention group 2: The second group of intervention is group B. The number of patients in this group is 30. The patients are given citalopram tablets made by Sobhan Pharmaceutical company at a dose of 10 mg in the first 10 days and then 20 mg daily ( which are poured into a capsule to be matched with a fluoxetine capsule) for 3 months. The NIHSS motor scale and drug side effect are assessed at the end of the first, second and third months.

**Category**

Treatment - Drugs

**3****Description**

Control group: This group is called group C, which has 30 patients. In addition to the standard treatment for ischemic stroke, placebo, which is starch and is poured into a capsule for assimilation with fluoxetine and citalopram, is given to one capsule daily for 3 months. At the end of the first, second and third months, the rate of improvement in motor function is assessed based on the NIHSS movement scale.

**Category**

Placebo

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Ayatollah Rouhani hospital ( Babol university of medical sciences)

**Full name of responsible person**

Fatemeh Karimi

**Street address**

Rouhani hospital, Ganjafroz Street, Babol, Mazandaran

**City**

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**Province**

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**Postal code**

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**Phone**

+98 11 3219 2034

**Email**

KARIMIF632@GMAIL.COM

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Babol University of Medical Sciences

**Full name of responsible person**

Babaei

**Street address**

Rouhani hospital, Ganjafroz Street, Babol, Mazandaran

**City**

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**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

**Title of funding source**

University

**Proportion provided by this source**

1

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding**

Academic

**Person responsible for general inquiries****Contact****Name of organization / entity**

Babol University of Medical Sciences

**Full name of responsible person**

Dr. Payam Saadat

**Position**

Neurologist and University faculty

**Latest degree**

Specialist

**Other areas of specialty/work**

Neurology

**Street address**

Rouhani hospital, Ganjafroz street, Babol, Mazandaran

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sepanta1968@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Babol University of Medical Sciences

**Full name of responsible person**

Dr. Payam Saadat

**Position**

Neurologist and faculty member of Babol University of Medical Sciences

**Latest degree**

Specialist

**Other areas of specialty/work**

Neurology

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Rouhani hospital, Ganjafroz street, Babol, Mazandaran

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Babol University of Medical Sciences

**Full name of responsible person**

Fatemeh Karimi

**Position**

Medical Intern

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

**Street address**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

Part of the data, such as information about the main outcome of the study, which is the rate of improvement in motor function, and its dependent variables

**When the data will become available and for how long**

After completing the study and after publishing the article

**To whom data/document is available**

Researchers working in academic centers

**Under which criteria data/document could be used**

The rate of improvement of motor function and analysis of related variables, evaluation of side effects

**From where data/document is obtainable**

Email the person in charge and the facilitator

**What processes are involved for a request to access data/document**

Request a study by email and provide sufficient evidence that the applicant is a university researcher.

**Comments**