

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

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

Babol University of Medical Sciences

Full name of responsible person

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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

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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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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

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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