Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Investigate the effect of fluoxetine and Citalopram on motor performance after stroke in acute stroke patients

Protocol summary

Study aim
Determining the effect of citalopram and fluoxetine on motor performance after stroke in acute cerebral stroke patients

Design
Randomized double-arm, double-blind, placebo-controlled

Settings and conduct
acute cerebral stroke patients

Participants/Inclusion and exclusion criteria
inclusion: age>18 Fugl-Meyer score<55 motor or sensory paralysis of half of the body after the first episode of acute stroke exclusion : Age over 70 years 2. National Institute of Health stroke score above 15 3. Previous disabilities including lack of speech, cognitive, and movement disorders caused by stroke or any disease of the cerebral cortex. 4. Pregnancy or breastfeeding 5. Current use of anti-depressant drugs 6. Kidney failure (glomerular filtration rate below 30 ml per minute) 7. Abnormal liver function tests 8. Hyponatremia and long TQ distance in the heart strip 9. Restlessness, increased pressure, or other manifestations of serotonin syndrome (after starting treatment)

Intervention groups
group A: The participants will receive a capsule containing 20 mg of fluoxetine orally once a day for 90 days, along with one hour of physiotherapy sessions a day, five days a week, for 21 weeks. Intervention group B: The participants will receive a capsule containing 20 mg of citalopram orally once a day for 90 days, along with physiotherapy for one hour a day, five days a week, for 21 weeks. Control group: Participants will receive a capsule containing microcrystalline cellulose as a placebo once a day for 90 days and physiotherapy for one hour a day, five days a week, for 21 weeks.

Main outcome variables
in the upper limb (shoulder flexion 90 to 180 degrees - grasping - pronation and supination of the hand - wrist flexion and extension, elbow extension - shoulder raising) in the lower limb (standing on one leg - knee flexion while standing،sitting - dorsiflexion of the leg- plantar flexion of the leg - hip flexion)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220810055657N1**
Registration date: **2022-09-03, 1401/06/12**
Registration timing: **registered_while_recruiting**

Last update: **2022-09-03, 1401/06/12**
Update count: **0**

Registration date
2022-09-03, 1401/06/12

Registrant information

Name
Vahid Dehghani MObarake

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 990 154 5294

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dehghani-v@kaums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-03-21, 1401/01/01

Expected recruitment end date
2023-03-20, 1401/12/29

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigate the effect of fluoxetine and Citalopram on motor performance after stroke in acute stroke patients

Public title

nvestigate the effect of fluoxetine and Citalopram on motor performance after stroke in acute stroke patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Over 18 years old motor or sensory paralysis of half of the body following the first episode of acute stroke (within the last 24 hours), cerebral ischemia Vogel-Meyer motor score below 55

Exclusion criteria:

Age over 70 years National Institute of Health stroke score above 15 Previous disabilities include: lack of speech, cognitive and movement disorders caused by stroke or any disease of the cerebral cortex. Pregnancy or breastfeeding Current use of antidepressants Kidney failure (glomerular filtration rate below 30 ml per minute) Abnormal liver function tests Hyponatremia and long TQ interval in heart strip Restlessness, increased pressure or other manifestations of serotonin syndrome (after starting treatment)

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

The method of randomization will be as follows: using the block randomization method (permuted block randomization) in such a way that first all 4 combinations of letters A and B are written (6 blocks) and numbers 1 to 6 for each block. considered and by randomly choosing numbers 1 to 6 from the table of random numbers; Its corresponding blocks will be written. This process of selection continues until the number of letters A and B reaches the required number of samples. After entering the study and completing the written consent form, the patient will receive a numerical code from 1 to 100 and from the table Prepared, which is available to the project manager, corresponding to the numerical code assigned to one of the drugs A or B. A and B groups will be randomly assigned to either fluoxetine or citalopram. It should be noted that regarding the variables of primary disability severity and other factors affecting the functional score, given that this study will be a clinical trial, randomization can largely control known or unknown confounding factors. (Due to the large sample size) statistical modeling also controls the effect of these factors on the outcome of the disease.

Blinding (investigator's opinion)

Double blinded

Blinding description

To blind, both drugs are in the form of capsules and will be filled and coded by the neurology resident in bottles that are identical in appearance; these codes will be entered into a table and will be decoded only after the end of the study, so the patient and The doctor will not know the type of medicine received and the treatment group.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee, School of Medicine and Dentistry, Kashan University of Medical Sciences

Street address

Qutb Rawandi Blvd

City

kashan

Province

Isfehan

Postal code

8715981151

Approval date

2021-11-16, 1400/08/25

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1400.117

Health conditions studied

1

Description of health condition studied

Acute stroke

ICD-10 code

I63.9

ICD-10 code description

Cerebral infarction, unspecified

Primary outcomes

1

Description

Motor function after acute stroke in patients

Timepoint

On the 90th day from the beginning of the study

Method of measurement

Fugl-Meyer movement scale

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Participants will receive capsules containing microcrystalline cellulose as a placebo orally once a day for 90 days along with physical therapy one hour a day, 5 days a week, for 21 weeks.

Category

Placebo

2

Description

Intervention group: A. Participants will receive capsules containing 20 mg of fluoxetine orally once daily for 90 days, along with physical therapy sessions of one hour per day, 5 days per week, for 21 weeks.

Category

Treatment - Drugs

3

Description

Intervention group: B . Participants will receive capsules containing 20 mg of citalopram orally once daily for 90 days along with physical therapy 1 hour per day, 5 days per week, for 21 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital, Kashan

Full name of responsible person

Dr. Vahid Dehghani

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

دکتر علی مسعود

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kashan University of Medical Sciences

Proportion provided by this source

100

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

Kashan University of Medical Sciences

Full name of responsible person

Dr. Vahid Dehghani

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Neurology

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Medical doctor

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no further information.

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available