Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Nov 2026

Evaluation of Fluoxetine and standard treatment efficacy on change to side effect of stroke of ischemic strokes in both hemisphers in anterior circulation

Protocol summary

Summary

Aim of this study is evaluation of Fluoxetine efficacy on change to side effect of ischemic strokes in both hemispheres in anterior circulation. This study is clinical trial and double blind. 60 patients with ischemic strokes in both hemispheres in anterior circulation will enter this study. We will divide patients in 4 groups randomly. We will prescribe standard treatment (drugs of Anti platelet and anticoagulant and Statin) and one capsule of 20 milligram Fluoxetine (Abidi drugs) in 15 patients with ischemic strokes in right hemisphere in intervention group. We will prescribe standard treatment (drugs of Anti platelet and anticoagulant and Statin) and placebo patients with ischemic strokes in right hemisphere in control group. We treat patient's with ischemic strokes in left hemisphere as right hemisphere. We complete National Institutes of Health Stroke Scale questionnaire in start study and first one and two months after treatment. Inclusion criteria: 40-70 years; both of gender; lack of history ischemic strokes and nerve focal defect in last; nerve focal defect in recent ischemic strokes Exclusion criteria: unavailability of patient during study period; history of side effect of Fluoxetine and other anti psychotic drugs; pregnant woman; lactating women

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017041720258N37**
Registration date: **2017-10-11, 1396/07/19**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-10-11, 1396/07/19

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor For Research, Arak University of Medical Sciences

Expected recruitment start date

2017-02-18, 1395/11/30

Expected recruitment end date

2019-03-21, 1398/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Fluoxetine and standard treatment efficacy on change to side effect of stroke of ischemic strokes in both hemisphers in anterior circulation

Public title

Evaluation of Fluoxetine efficacy on change to side effect of ischemic strokes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 40-70 years; both of gender; lack of history ischemic strokes and nerve focal defect in last; nerve focal defect in recent ischemic strokes; compatibility clinical symptoms of stroke and place conflict brain imaging; select patient in 2-7 days after start ischemic strokes Exclusion criteria: unavailability of patient during study period; history of side effect of Fluoxetine and other anti psychotic drugs; pregnant woman; lactating women; depression and recent depression in one month ago and treatment with anti psychotic drugs; use Monoamine oxidase inhibitorin five months ago

Age

From **40 years** old to **70 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

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

Ethics committee Arak University Of Medical Sciences

Street address

Vice chancellor for research, Payambar azam complex, Basij squre, Sardasht, Arak

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38149578558

Approval date

2017-01-30, 1395/11/11

Ethics committee reference number

IR.ARAKMU.REC.1395.376

Health conditions studied

1

Description of health condition studied

Ischemic strokes

ICD-10 code

G46.4*

ICD-10 code description

Cerebellar stroke syndrome

Primary outcomes

1

Description

change to side effect of stroke

Timepoint

start study and first one and two months after treatment

Method of measurement

National Institutes of Health Stroke Scale questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

We will prescribe patients one capsule of 20 milligram Fluoxetine (Abidi drugs)and standard treatment (drugs of Anti platelet and anticoagulant and Statin) in intervention group .

Category

Treatment - Drugs

2

Description

We will treatment patients standard treatment (drugs of Anti platelet and anticoagulant and Statin) and placebo in control group.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr Hospital

Full name of responsible person

Dr Mohsen Ebrahimi Monfared

Street address

Valiasr Hospital, Arak

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Arak University of Medical Sciences

Full name of responsible person
Dr Mohammad Rafiee

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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
Vice chancellor for research, Arak University of Medical Sciences

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