

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

A Survey for Assessment of Effectiveness of Fluoxetine on Motor Improvement in Ischemic Stroke Patients

Protocol summary

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Summary

This study accomplishes on the patients with motor deficit from stroke that are admitted in Emam Reza hospital. Patients divide to two groups accidentally, group A : case (that take fluoxetine) and group B: control(that take placebo).Before use of drug,we fill a motor scale (Barthe Index(BI)) and a psychiatric index(Hamilton Depression Rating Scale(HDRS)) for each patient.whole time of treatment is 90 days and during this period patients is treated with 30 course of physiotherapy during admission and after discharge . In day 45 and 90 patients reexamine and the noted scales(BI and HDRS) will fill for them.

Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Science

Expected recruitment start date

2013-03-20, 1391/12/30

Expected recruitment end date

2014-04-21, 1393/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201312088323N7**

Registration date: **2014-01-09, 1392/10/19**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-01-09, 1392/10/19

Registrant information

Name

Nazanin Razazian

Name of organization / entity

Neurology Department of Kermanshah Faculty of Medicine

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Email address

Scientific title

A Survey for Assessment of Effectiveness of Fluoxetine on Motor Improvement in Ischemic Stroke Patients

Public title

A Survey for Assessment of Effectiveness of Fluoxetine on Motor Improvement in Ischemic Stroke Patients

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: stroke in middle cerebral artery(documented with imaging) and the patient have a hemi or mono plegy or paresis:the patient was not comatose : filling the agreement sheet with patient or a reliable attendant : the patient is dischargable and not admitted in ICU ward exclusion criteria: death of patient with any cause in duration of study : irregular use of drugs : irregular return for reexaminations : presence of seizure, severe diarrhea, vomiting, severe insomnia : presence of metabolic disorder(hyperthyroidism, hepatic , renal, cardiac,...) : past medical history of psychiatric disorder or severe depression before stroke : presence of SAH, lobar ICH, brain tumor : stroke in other vascular territories (MCA, ACA,...) : simultaneous use of MAO-i ,

Selegiline, Cyproheptadine.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 150

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kermanshah University of Medical Science

Street address

Shahid beheshti boulevered- building no.2 - reserch adjutancy

City

Kermanshah

Postal code

-

Approval date

2013-09-11, 1392/06/20

Ethics committee reference number

34739

Health conditions studied

1

Description of health condition studied

stroke

ICD-10 code

G46.0

ICD-10 code description

Middle cerebral artery syndrome

Primary outcomes

1

Description

motor deficit and psychiatric disorder

Timepoint

before study, day 45, day 90

Method of measurement

Hamilton depression rating Scale(HDRS) for psychiatric disorders and Barthel Index(BI) for motor assessment.

Secondary outcomes

empty

Intervention groups

1

Description

In case group we prescribed cap fluoxetine, 20 mg, P.O. one time a day for 90 days.

Category

Treatment - Drugs

2

Description

In control group we prescribe a capsule with same size and color to fluoxetine ,(as placebo) for 90 days.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Kermanshah- Emam reza hospital

Full name of responsible person

Omid Esmaeili M.D.

Street address

Emam Reza hospital

City

kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Science

Full name of responsible person

Mr. Shirzadian

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Shahid Beheshti boulevered- building no.2 -research center

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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

Kermanshah University of Medical Science

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**

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Full name of responsible person

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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