Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effect of Fluxetine on Fatigue,sleep quality and depression in Patients with Multiple Sclerosis

Protocol summary

Summary

The aim of the present study was to determine the anti-inflammatory effects of fluoxetine on fatigue in patients with relapsing MS and also to survey the changes in sleep quality and depression In a triple-blind, placebo-controlled exploratory study, 60 non-depressed patients with relapsing remitting MS were randomized to oral fluoxetine 20 mg or placebo daily for 24 weeks. fatigue, sleep quality and depression evaluation performed on weeks 1 and 24 by assessing FSS(Fatigue Severity Scale), PSQI(Pittsburgh Sleep Quality Index) and BDI(Beck Depression Inventory).Clinical activity of MS was also studied by assessing EDSS (Expanded Disability Status Scale)

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014062017811N3**
Registration date: **2014-06-22, 1393/04/01**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-06-22, 1393/04/01

Registrant information

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Recruitment status

Recruitment complete

Funding source

Office of Vice Chancellor for Research

Expected recruitment start date

2013-07-02, 1392/04/11

Expected recruitment end date

2014-06-01, 1393/03/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Fluxetine on Fatigue,sleep quality and depression in Patients with Multiple Sclerosis

Public title

fluoxetine AND Multiple sclerosis

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: age 18–50 yearsپ ؛clinically definitive relapsing remitting MS((according to the 2005 revised McDonald criteria)confirmed by a neurologist ؛ Additional inclusion criteria were an Expanded disability Status Score (EDSS) of less or equal to 5.5 ؛ exclusion criteria: progressive forms of multiple sclerosis ؛ an onset of relapse or receipt of any glucocorticoid treatment during trial period ؛ use of immunomodulatory, immunosuppressive, IVIg or plasmapherasis or antidepressant drugs in the previous 6 months؛ the use of corticosteroids in the previous 8 weeks ؛ depression defined as a score of 19 or higher on Beck’s Depression Inventory II ؛contraindication to MRI ؛ other neurological or systemic disorder that would interfere with the

assessments ؛ pregnancy or unwillingness to use acceptable birth control. severe suicidality including ideation, plan, and intentclinically significant ؛ unstable medical or surgical conditions that would preclude safe and complete participation in the study.

Age
From **18 years** old to **50 years** old

Gender
Both

Phase
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)
Triple blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Arak University of medical science

Street address
Arak University of medical science,sardasht,arak,iran

City
Arak

Postal code

Approval date
2013-02-02, 1391/11/14

Ethics committee reference number
92-143-10

Health conditions studied

1

Description of health condition studied
Multiple Sclerosis

ICD-10 code
G35

ICD-10 code description
Demyelinating diseases of the central nervous system

Primary outcomes

1

Description
fatigue

Timepoint
week 0 and 24

Method of measurement
FSS(fatigue severity scale) test

2

Description
sleep quality

Timepoint
week 0 and 24

Method of measurement
PSQI test

3

Description
depression

Timepoint
week 0 and 24

Method of measurement
BDI(BECK depression inventory)

Secondary outcomes

1

Description
Clinical status

Timepoint
week 0 and 24

Method of measurement
EDSS (Expanded Disability Status Scale)

Intervention groups

1

Description
oral flouxetine 20 mg for 24 weeks will be given to patient whom randomised to intervention group

Category
Treatment - Drugs

2

Description
patients whom randomized to placebo group will received placebo capsules during 24 weeks of clinical trial course

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Neurology clinic of valiasr hospital-Arak MS society-private offices

Full name of responsible person
Dr.Fardin Faraji

Street address

City
Arak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Arak University of Medical Science,Office of Vice Chancellor for Research

Full name of responsible person
Davoud Hekmatpo

Street address
Arak univercity of medical science , Arak , Iran

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Grant name
22100000 ریال

Grant code / Reference number
907

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

Title of funding source
Arak University of Medical Science,Office of Vice Chancellor for Research

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

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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