Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

A Comparative Study between Sodium Valproate and Fluoxetine in patient with migraine and chronic fatigue syndrome

Protocol summary

Summary

Objectives:The aim of this research is a comparison between Sodium Valproate and Fluoxetine in patient with migraine and chronic fatigue syndrome. Design:This is a clinical trial and 64 patients with migraine and chronic fatigue syndrome has been studied.They divided into two group with 32 participates randomly.The blinding was not done.The study was in phase 2. Setting and conduct:Each group separately take the treatment with Sodium Valproate 400mg daily and Fluoxetine 20mg daily.After 8 weeks of treatment,the groups compare with each other by headache intensity score and headache frequency. Participants including major eligibility criteria: All the patients with migraine whom were examined by neurologist and have chronic fatigue syndrome too.The diagnose of migraine and chronic fatigue syndrome was on the base of ICHD and NICE criteria. Intervention:A 8 week treatment with Sodium Valproate 400mg daily and Fluoxetine 20mg daily was done. main outcome measures:The headache intensity score and headache frequency was measured before and after 8 week of treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016062828680N1**
Registration date: **2016-07-19, 1395/04/29**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-07-19, 1395/04/29

Registrant information

Name

Mahdis Khazaeli

Name of organization / entity

Esfahan

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Isfahan University of Medical Sciences

Expected recruitment start date

2014-03-21, 1393/01/01

Expected recruitment end date

2014-08-23, 1393/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Comparative Study between Sodium Valproate and Fluoxetine in patient with migraine and chronic fatigue syndrome

Public title

Comparison between Sodium Valproate and Fluoxetine in patient with migraine and chronic fatigue syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: migraine;chronic fatigue syndrome
Exclusion criteria:The incidence of drug side effects;Individual may not adhere;Individual may not complete follow up

Age
From **20 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **64**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethic Committee of Isfahan University of Medical Science
Street address
Isfahan University of Medical Sciences, Isfahan, Hezar Jarib Ave.
City
Isfahan
Postal code
Approval date
2014-01-22, 1392/11/02
Ethics committee reference number
393292

Health conditions studied

1

Description of health condition studied
Migraine
ICD-10 code
G43
ICD-10 code description
Migraine

Primary outcomes

1

Description
intensity score of headache
Timepoint
8 weeks
Method of measurement
VAS score

2

Description
frequency of headache
Timepoint
8 weeks
Method of measurement
headaches attacks per week

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group with Fluoxetine tab 20 mg daily
Category
Treatment - Drugs

2

Description
Intervention group with Sodium Valproat Tan 200 mg BID
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Isfahan Alzahra Hospital
Full name of responsible person
Mahdis Khazaeli
Street address
No. 5, Ghayoor Alley, Imam St., Najafabad, Isfahan
City
Najafabad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor Of Research, Isfahan University of Medical Sciences
Full name of responsible person
Mahdi Nematbakhsh
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Vice Chancellor Of Research, Building No. 4, Isfahan University of Medical Sciences, Hezarjerib St., Isfahan

City
Isfahan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor Of Research, Isfahan 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

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