

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Investigating the effect of fenofibrate for seizure control in refractory epilepsy patients

Protocol summary

Study aim

Determining the effect of fenofibrate for seizure control in refractory epilepsy patients

Design

A randomized, double-blinding clinical trial, with A single-group, Phase 2 on 30 patients

Settings and conduct

In this randomized double-blind clinical trial study, 30 eligible patients, referring to Al-Zahra and Kashani hospitals in Isfahan, will be included. For all patients, the dosage of the fenofibrate drug starts at 100 mg per day; if the seizures are not controlled, it is increased to 200 mg per day after two weeks. The intervention will be performed in such a way that the patient, the researcher, and the statistical analyst will have no knowledge of the type of intervention. Then the parameters related to seizures of the patients before and after the intervention will be compared.

Participants/Inclusion and exclusion criteria

The inclusion criteria include patients with epilepsy, age older than 18 years, resistance to at least two anticonvulsant drugs, having seizures on average twice a month or more, and consenting to participate in the study. Exclusion criteria include concurrent liver and kidney disease, hyperlipidemia, and atorvastatin drug use.

Intervention groups

In this study, only one group is treated. In this group, the dosage of the fenofibrate drug starts at 100 mg daily, and if the seizures are not controlled, it is increased to 200 mg per day after two weeks.

Main outcome variables

Number of seizure attacks, EEG changes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200825048515N63**

Registration date: **2023-01-17, 1401/10/27**

Registration timing: **prospective**

Last update: **2023-01-17, 1401/10/27**

Update count: **0**

Registration date

2023-01-17, 1401/10/27

Registrant information

Name

Asieh Maghami Mehr

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 0000 0000

Email address

asimaghami@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-19, 1401/11/30

Expected recruitment end date

2023-07-22, 1402/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of fenofibrate for seizure control in refractory epilepsy patients

Public title

The effect of fenofibrate for seizure control in epilepsy

patients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Epilepsy patients Age more than 18 years Resistant to at least two anticonvulsants Having seizures on average twice a month or more Consent to participate in the study

Exclusion criteria:
Concurrent liver and kidney disease and hyperlipidemia Atorvastatin drug use

Age
From **18 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, 30 eligible patients will be selected randomly and all will undergo a specific treatment. The present study does not have a control group.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, fenofibrate drug is prepared and provided to the researcher, and he prescribes it without knowing the type of drug. Also, the person recording the patient's clinical information and the statistical analyst will not be aware of the type of intervention.

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address

Isfahan University of Medical Sciences, Hezar Jarib Street, Azadi Square

City
Isfahan

Province
Isfahan

Postal code
8179964167

Approval date
2022-09-07, 1401/06/16

Ethics committee reference number
IR.MUI.MED.REC.1401.221

Health conditions studied

1

Description of health condition studied

Refractory epilepsy

ICD-10 code
G40.91

ICD-10 code description
Epilepsy, unspecified, intractable

Primary outcomes

1

Description
Number of seizure attacks

Timepoint
Before and after the intervention

Method of measurement
Seizure attack frequency

2

Description
EEG changes

Timepoint
Before and after the intervention

Method of measurement
Electrocardiogram (ECG)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In this group, the dosage of fenofibrate drug starts with 100 mg daily, and if the seizures are not controlled, it is increased to 200 mg per day after two weeks.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Hospital

Full name of responsible person

Mohammad Reza Najafi

Street address

Hezar Jarib Street.

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Najafi@med.mui.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Gholamreza Askari

Street address

Vice Chancellor for Research, School of Medicine,
Hezar Jarib Street, Isfahan

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8174673461

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Grant name

Grant code / Reference number

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

No

Title of funding source

Isfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Mohammad Reza Najafi

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Neurology

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Neurology Department, Al-Zahra Hospital, Hezar Jarib
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Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mohammad Reza Najafi

Position

Professor

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mahsa Salimyan

Position

Non-faculty specialist doctor

Latest degree

Subspecialist

Other areas of specialty/work

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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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available