Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

Isfehan

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.

City
Isfahan

Province
Isfehan

Postal code
8179964167

Phone
+98 31 3651 3337

Email
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

City
Isfahan

Province
Isfehan

Postal code
8174673461

Phone
+98 31 3668 8597

Email
dean@med.mui.ac.ir

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

Street address
Neurology Department, Al-Zahra Hospital, Hezar Jarib Street

City
Isfahan

Province
Isfehan

Postal code
8174675731

Phone
+98 31 3620 2020

Email
Najafi@med.mui.ac.ir

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

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Neurology

Street address
Neurology Department, Al-Zahra Hospital, Hezar Jarib Street

City
Isfahan

Province
Isfehan

Postal code
8174675731

Phone
+98 31 3620 2020

Email
Najafi@med.mui.ac.ir

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
Neurology
Street address
Neurology Department, Al-Zahra Hospital, Hezar Jarib Street
City
Isfahan
Province
Isfehan
Postal code
8174675731
Phone
+98 31 3620 2020
Email
mahsasalimyan1@gmail.com

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