Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

A clinical trial to compare the effectiveness of dimethyl fumarate in multiple sclerosis patients before and after intervention.

Protocol summary

Study aim
A clinical trial to compare the effectiveness of dimethyl fumarate in multiple sclerosis patients before and after intervention.

Design
This clinical trial with a before and after treatment design of 40 patients with multiple sclerosis were assigned base on community-based setting.

Settings and conduct
The study population will be selected from the patients with multiple sclerosis referring to Multiple Sclerosis Central Committee, Mashhad University of Medical Sciences, Mashhad, Iran, and will be administered dimethyl fumarate for treatment.

Participants/Inclusion and exclusion criteria
Inclusion criterion: patients with relapsing-remitting multiple sclerosis. Exclusion criteria: having a blood and liver failure; discontinuation of treatment cause of disruption in laboratory tests.

Intervention groups
The intervention group will receive 240 mg dimethyl fumarate twice a day for one year.

Main outcome variables
Number and severity of attacks based on expanded disability status scale (EDSS) score and the number of magnetic resonance imaging (MRI) lesions based on brain MRI before and one year after intervention

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20190121042439N1**
Registration date: **2019-02-02, 1397/11/13**
Registration timing: **prospective**

Last update: **2019-02-02, 1397/11/13**
Update count: **0**

Registration date
2019-02-02, 1397/11/13

Registrant information
Name
Sahar Gazeran
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-02-20, 1397/12/01
Expected recruitment end date
2020-04-20, 1399/02/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A clinical trial to compare the effectiveness of dimethyl fumarate in multiple sclerosis patients before and after intervention.

Public title
The reduction in the number of attacks in multiple sclerosis patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:

Patients with relapsing-remitting multiple sclerosis

Exclusion criteria:

History of blood diseases Liver failure Discontinuation of treatment cause of disruption in laboratory tests

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

Street address

Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street

City

Mashhad

Province

Razavi Khorasan

Postal code

9195965919

Approval date

2017-11-08, 1396/08/17

Ethics committee reference number

IR.MUMS.fm.REC.1396.475

Health conditions studied

1

Description of health condition studied

Multiple sclerosis patients

ICD-10 code

G35

ICD-10 code description

Multiple sclerosis

Primary outcomes

1

Description

Number and severity of attacks

Timepoint

Before and one year after intervention

Method of measurement

Expanded disability status scale (EDSS) score

Secondary outcomes

1

Description

The number of magnetic resonance imaging (MRI) lesions

Timepoint

Before and one year after intervention

Method of measurement

Brain MRI

Intervention groups

1

Description

Intervention group: The intervention group will receive 240 mg dimethyl fumarate twice a day for one year.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Multiple Sclerosis Central Committee

Full name of responsible person

Sahar Gazeran

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Imam Reza Hospital, Imam Reza Square

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghodi
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vcresearch@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences
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Sahar Gazeran
Position
Resident
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

The total data to be included are the primary and secondary effects to be shared.

When the data will become available and for how long

6 months after printing results

To whom data/document is available

Our data will only be available to researchers working in science center and university.

Under which criteria data/document could be used

Our data will be available for scholars working in science center and university.

From where data/document is obtainable

Sahar Gazeran provides the analysis code to the applicants via email: Gazerans941@mums.ac.ir

What processes are involved for a request to access data/document

Data collection was done for 10 months, data were collected one month, statistical analysis of one month, information dissemination as a article six months.

Comments