

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

25 Jun 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

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 3854 3031

###### Email address

gazerans941@mums.ac.ir

##### 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

**Street address**

Imam Reza Hospital, Imam Reza Square

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9137913316

**Phone**

+98 51 3854 3031

**Email**

Gazerans941@mums.ac.ir

**Web page address**

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Mohsen Tafaghodi

**Street address**

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

**City**

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**Postal code**

913753459

**Phone**

+98 51 3841 1538

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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

**Full name of responsible person**

Sahar Gazeran

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Neurology

**Street address**

Imam Reza Hospital, Imam Reza Square

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## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

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**Full name of responsible person**

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**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

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## Person responsible for updating data

**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Sahar Gazeran

**Position**

Resident

**Latest degree**

Medical doctor

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Neurology

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**Email**

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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**