

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparing the effect of Dimethyl fumarate and Placebo on infarct size and NIHSS score in acute ischemic stroke patients

#### Protocol summary

##### Study aim

1. Comparing the effect of dimethyl fumarate and Placebo on NIHSS score of patients, before and after the trial
2. Comparing the effect of dimethyl fumarate and Placebo on infarct size of patients, before and after the trial
3. finding a suitable drug for reducing disabilities among stroke patients

##### Design

The study is two arm parallel group, double blinded, randomized clinical trial

##### Settings and conduct

Patients who are admitted the Shariati hospital will be assigned to the trial according to the inclusion and exclusion criteria. Then they undergo a clinical examination and an MRI scan will be carried out for them at the beginning of the trial. Then they will be divided into Placebo or Drug groups according to the randomization table. There will be 16 patients in each group. Another examination and MRI will be carried out 15 to 45 days after the first dose of drug/placebo. The patients and the doctor are both blind to the drug/placebo groups.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients at the age of 18-85 years old; Patients with acute neurological symptoms that have been diagnosed as ischemic stroke patient by a neurologist. Non inclusion criteria: Patients with prior sensitivity to dimethyl fumarate; Patients with serious infections; Pregnancy and lactation; Immunologic deficiencies in the past 6 months; Patients receiving rtPA; Patients who undergo endovascular treatment.

##### Intervention groups

Intervention group: the group receiving 240mg Dimethyl fumarate, three times a day for one week. Control group: the group receiving Placebo, three times a day for one week

##### Main outcome variables

Infarct size; National Institute of Health Stroke Scale(NIHSS)

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180224038841N1**

Registration date: **2019-01-13, 1397/10/23**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-01-13, 1397/10/23**

Update count: **0**

##### Registration date

2019-01-13, 1397/10/23

##### Registrant information

##### Name

Seyed Mehrdad Savar

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8822 0040

##### Email address

sm-savar@student.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-12-31, 1397/10/10

##### Expected recruitment end date

2019-04-09, 1398/01/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparing the effect of Dimethyl fumarate and Placebo on infarct size and NIHSS score in acute ischemic stroke patients

**Public title**

Evaluation of efficacy of Dimethyl Fumarate in stroke

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patients at the age of 18-85 years old Patients with acute neurological symptoms who have been diagnosed as ischemic stroke by a neurologist

**Exclusion criteria:**

Patients with prior sensitivity to dimethyl fumarate  
Patients with serious infections Pregnancy and lactation  
Immunologic deficiencies in the past 6 months (i.e. cancer, lymphoma, HIV and viral hepatitis)  
Patients receiving rtPA  
Patients who undergo endovascular treatment  
Liver function test more than 2 times of normal range  
Initial WBC count under 3500  
Lymphopenia under 500

**Age**

From **18 years** old to **85 years** old

**Gender**

Both

**Phase**

2

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **32**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

According to the table of random numbers patients are assigned to drug or placebo group.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

It's a double blind clinical trial. The care provider, the outcome assessor, the patients and the investigator are all blind. The drugs are labeled by "A" and "B" and the process of labeling the drugs (dimethyl fumarate and placebo) with "A" and "B" is done by a clinical pharmacist who is not involved in any other process in the trial.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Tehran University of Medical Sciences

**Street address**

Central Headquarters of Tehran University of Medical Sciences, Keshavarz Blvd. and Ghodss St. Intersection

**City**

Tehran

**Province**

Tehran

**Postal code**

1417653761

**Approval date**

2018-02-21, 1396/12/02

**Ethics committee reference number**

IR.TUMS.PSRC.REC.1396.4572

**Health conditions studied****1****Description of health condition studied**

Ischemic Stroke

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Infarct Size in Magnetic Resonance Imaging(MRI)

**Timepoint**

An MRI at the beginning of the trial and a second one after 15 to 45 days from starting Dimethyl fumarate or Placebo

**Method of measurement**

using automatic softwares

**2****Description**

National Institute of Health Stroke Scale (NIHSS)

**Timepoint**

at the beginning of the trial and 30 days after starting Dimethyl fumarate

**Method of measurement**

NIHSS checklist

**Secondary outcomes**

empty

**Intervention groups**

## 1

### Description

Intervention group: Dimethyl fumarate 240mg , three times a day for one week

### Category

Treatment - Drugs

## 2

### Description

Control group: Placebo , three times a day for one week

### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shariati Hospital

##### Full name of responsible person

Dr. Siamak Abdi

##### Street address

Shariati Educational Research Center, Jalal Al Ahmad three way, North Kargar street

##### City

Tehran

##### Province

Tehran

##### Postal code

1411713135

##### Phone

+98 21 8490 1000

##### Fax

+98 21 8863 3039

##### Email

shariatihosp@tums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Dr. Mohammadali Sahraeian

##### Street address

Central Headquarters of Tehran University of Medical Sciences, at the corner of Qods street, Keshavarz boulevard and Qods street intersection

##### City

Tehran

##### Province

Tehran

##### Postal code

1417653761

##### Phone

+98 21 8163 3686

##### Email

rcco@tums.ac.ir

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Tehran 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

Tehran University of Medical Sciences

##### Full name of responsible person

Seyed Mehrdad Savar

##### Position

Student

##### Latest degree

A Level or less

##### Other areas of specialty/work

Medical Pharmacy

##### Street address

Neurology ward, first floor, Shariati Hospital, Jalal Al Ahmad three way, North Kargar street

##### City

Tehran

##### Province

Tehran

##### Postal code

1411713135

##### Phone

+98 21 8822 0040

##### Fax

##### Email

mehrdad.savar@gmail.com

## Person responsible for scientific inquiries

#### Contact

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Tehran University of Medical Sciences

##### Full name of responsible person

Seyed Mehrdad Savar

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Student

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**Person responsible for updating data****Contact****Name of organization / entity**

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**Fax****Email**

mehrdad.savar@gmail.com

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

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

**Statistical Analysis Plan**

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

**Informed Consent Form**

No - There is not 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**

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

**Title and more details about the data/document**

only the data related to the main and secondary objectives of the study can be shared.

**When the data will become available and for how long**

Starting access 3 months after publication

**To whom data/document is available**

only available for people working at academic institutions and universities

**Under which criteria data/document could be used**

the request must be sent to the corresponding author by email and it will be decided per case.

**From where data/document is obtainable**

By sending the request for the corresponding author through an email.

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

The reason of asking for the data along with the request for the data must be sent to the corresponding author via email. After evaluating the reason for asking the data, the data will be provided if possible.

**Comments**