

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### The evaluation of the Effect of Fingolimod on Fatigue and depression in patients with Multiple Sclerosis

#### Protocol summary

##### Summary

General Objective: Evaluation of the Effect of Fingolimod on fatigue and depression in patients with Multiple Sclerosis. Study Design: Single arm study (before and after). Main Inclusion Criteria: 18-50 years of age; relapsing remitting multiple sclerosis; disease must not be in its acute phase. Main Exclusion Criteria: Any underlying pulmonary, hepatic, renal or orthopedic disorder; EDSS score > 5.5; natural events causing depression happen to the patient during follow up period. Target sample size: 40. Fatigue Severity Scale and Beck's depression questionnaire at 0, 3 and 6 month intervals must be obtained from the patients. Study outcomes: Effects of the Fingolimod on degree of fatigue and depression.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201407018323N11**

Registration date: **2016-01-23, 1394/11/03**

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

Last update:

Update count: **0**

##### Registration date

2016-01-23, 1394/11/03

##### Registrant information

##### Name

Nazanin Razazian

##### Name of organization / entity

Neurology Department of Kermanshah Faculty of Medicine

##### Country

Iran (Islamic Republic of)

##### Phone

+98 83 1427 3409

##### Email address

nrazazian@kums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Kermanshah University of Medical Sciences

##### Expected recruitment start date

2016-01-21, 1394/11/01

##### Expected recruitment end date

2016-03-19, 1394/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The evaluation of the Effect of Fingolimod on Fatigue and depression in patients with Multiple Sclerosis

##### Public title

The evaluation of the Effect of Fingolimod on Fatigue and depression in patients with M.S

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion Criteria: age 18-50 years; definite M.S confirmed by neurologist with relapsing remitting type; disease must be in remission; at least one month after corticosteroid therapy; follow up should be possible and patients must be reachable. exclusion criteria: any underlying pulmonary, hepatic, renal or orthopedic; EDSS score > 5.5; during follow up events that affect depression happen to the patients.

##### Age

From **18 years** old to **50 years** old

##### Gender

Both

## Phase

N/A

## 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

Deputy of Research and Technology of Kermanshah  
University of Medical Sciencesarch and technology

##### Street address

Building number 2, Kermanshah University of Medical  
Sciences,shahid beheshti bulevard

##### City

Kermanshah

##### Postal code

#### Approval date

2015-01-13, 1393/10/23

#### Ethics committee reference number

45249

## Health conditions studied

### 1

#### Description of health condition studied

multiple sclerosis

#### ICD-10 code

G35

#### ICD-10 code description

multiple sclerosis

## Primary outcomes

### 1

#### Description

fatigue severity

#### Timepoint

before intervention,3 months after initiation of  
intervention,6 months after initiation of intervention

#### Method of measurement

fatigue severity scale

### 2

#### Description

degree of depression

#### Timepoint

before intervention,3 months after initiation of  
intervention,6 months after initiation of intervention

#### Method of measurement

beck standard questionnaire

## Secondary outcomes

### 1

#### Description

Liver enzymes concentrations

#### Timepoint

Before initiation of study,every month for the first 3  
months,then every 3 months so on

#### Method of measurement

Liver function test

### 2

#### Description

Lymphositic count

#### Timepoint

Before initiation of study,every month for the first 3  
months,then every 3 months after

#### Method of measurement

CBD-diff

## Intervention groups

### 1

#### Description

Fingolimode,0.5 mg,once daily,oral,for 6 months

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Neurology ward,Kermanshah Emam Reza grand  
hospital

##### Full name of responsible person

Faezeh Nalchi

##### Street address

Kermanshah Emam Reza grand hospital, Daneshgah  
street, Shahid Shiroodi BLV

##### City

Kermanshah

## Sponsors / Funding sources

## 1

### Sponsor

**Name of organization / entity**

Deputy of Research and Technology of Kermanshah University of Medical Sciences

**Full name of responsible person**

Hamzehee Kourosh

**Street address**

Building number 2, Kermanshah University of Medical Sciences,shahid beheshti boulevard

**City**

Kermanshah

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Deputy of Research and Technology of Kermanshah University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

*empty*

### Person responsible for general inquiries

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

Kermanshah University of Medical Sciences, medical faculty

**Full name of responsible person**

Faezeh Nalchi

**Position**

medical doctor(PHD)/neurology resident

**Other areas of specialty/work****Street address**

school of medicine, Daneshgah street, Shahid Shiroodi boulevard

**City**

Kermanshah

**Postal code**

6714869914

**Phone**

+98 834274620

**Fax****Email**

mcollege@kums.ac.ir

**Web page address**

### Person responsible for scientific inquiries

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

Kermanshah University of Medical Sciences, medical faculty

**Full name of responsible person**

Razazian Nazanin

**Position**

medical doctor,neurologist

**Other areas of specialty/work****Street address**

school of medicine, Daneshgah street, Shahid Shiroodi boulevard

**City**

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**Postal code****Phone**

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mcollege@kums.ac.irnazazian@kums.ac.irnazazian@gmail.com

**Web page address**

### Person responsible for updating data

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

Kermanshah University of Medical Sciences, medical faculty

**Full name of responsible person**

Faezeh Nalchi

**Position**

medical doctor(PHD)/neurology resident

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school of medicine, Daneshgah street, Shahid Shiroodi boulevard

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Kermanshah

**Postal code****Phone**

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**Fax****Email**

mcollege@kums.ac.irfaezeh.nalchi@gmail.com

**Web page address**

### Sharing plan

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

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*