

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

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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

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

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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

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Razazian Nazanin

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Web page address

Person responsible for updating data

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Kermanshah University of Medical Sciences, medical faculty

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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