Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 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 questionare 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 corticostroid therapy; follow up shouldbe 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 questionare

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 bulevard

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 bulevard

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 bulevard

City
Kermanshah

Postal code

Phone
+98 834274620

Fax

Email
mcollege@kums.ac.irnrazazian@kums.ac.irnrazazian@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Kermanshah University of Medical Sciences, medical faculty

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Faezeh Nalchi

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medical doctor(PHD)/neurology resident

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Kermanshah

Postal code

Phone
+98 834274620

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