

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

Effectiveness and side effects of fingolimod in 3-year follow-up of patients with relapsing- remitting multiple sclerosis(RRMS)

Protocol summary

Summary

This study will be done with aim to study the effectiveness and long-term side effects of biosimilar fingolimod oral forms in 3-year follow-up of patients with RRMS. This is non-blinded clinical trial. The study population will be consisted of all women with RRMS referred to the MS clinic of Imam Reza Hospital. A total of 50 patients with RRMS according to the recurrence of MS despite treatment with first-line drugs DMT are candidates for treatment with fingolimod by a neurologist; And from the 23/9/2013 received fingolimod and new patients that are candidate to receive fingolimod form 23/9/2015 until 20/9/2016 will be selected in available method. Baseline (at least 6 hours after admission) ECG results, heart rate and blood pressure will be recorded in the checklist. Patients will receive half-mg biosimilar fingolimod oral capsule daily and for two years, for the symptoms, elevated liver enzymes, and the degree of white blood cells will be examined every three months. At the end treatment satisfaction questionnaire for drugs will be provided for patients and their satisfaction will be measured. Inclusion criteria: Age 18-45 years; EDSS score between 0 and 5.5; Negative pregnancy test for women of childbearing age. Exclusion criteria: macular edema at baseline; History of treatment with cyclophosphamide or mitoxantrone at any time; Breastfeeding and pregnancy; Full or direct bilirubin greater than the upper limit of normal; Creatinine more than 1.7 mg per deciliter

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201705108323N15**

Registration date: **2017-06-07, 1396/03/17**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-06-07, 1396/03/17

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

Vice chancellor for research, Kermanshah University of Medical Sciences

Expected recruitment start date

2013-09-23, 1392/07/01

Expected recruitment end date

2017-09-21, 1396/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness and side effects of fingolimod in 3-year follow-up of patients with relapsing- remitting multiple sclerosis(RRMS)

Public title

Evaluating the efficacy and side effects fingolimod in 3 -

year follow-up of patients with recurrent forms of multiple sclerosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age 18-45 years; EDSS score between 0 and 5.5; At least one relapse in the previous year despite treatment with a variety of first-line DMT; At least two relapses in the past two years despite treatment with a variety of first-line DMT; No relapse in the 30 days before starting treatment with fingolimod; Negative pregnancy test for women of childbearing age. Exclusion criteria: macular edema at baseline; acute or chronic active bacterial infection, fungal or Viral; Treatment with intravenous corticosteroids within 30 days prior to the start fingolimod; History of treatment with cyclophosphamide or mitoxantrone at any time; Breastfeeding and pregnancy; AST and ALT more than double upper limit of normal; Full or direct bilirubin greater than the upper limit of normal; Creatinine more than 1.7 mg per deciliter; White blood cells below 3500 per cubic millimeter; Lymphocyte count below 800 per cubic millimeter; The presence of uveitis

Age

From **18 years** old to **45 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

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 Kermanshah University of Medical Sciences

Street address

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

City

Kermanshah

Postal code**Approval date**

2017-03-08, 1395/12/18

Ethics committee reference number

kums.rec.1395.753

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

Multiple Sclerosis

ICD-10 code

G35

ICD-10 code description

Demyelinating diseases of the central nervous system

Primary outcomes**1****Description**

Blood pressure

Timepoint

Baseline, every three months for two years

Method of measurement

Blood pressure meter

2**Description**

White blood cells

Timepoint

Baseline, every three months for two years

Method of measurement

By blood tests in the laboratory

3**Description**

Progressive multifocal leukoencephalopathy

Timepoint

Baseline, every three months for two years

Method of measurement

Using MRI

4**Description**

Liver enzymes

Timepoint

Baseline, every three months for two years

Method of measurement

By blood tests in the laboratory

Secondary outcomes

empty

Intervention groups

1

Description

In intervention group patients will receive half-mg biosimilar fingolimod oral capsule daily

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Hospital

Full name of responsible person

Dr. Masomeh Moaref

Street address

Emam Reza Hospital, Parastar Boulevard

City

Kermanshh

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Kermanshah University of Medical Sciences

Full name of responsible person

Koroush Hamzehee

Street address

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

City

Kermanshah

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, 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

Full name of responsible person

Dr. Masomeh Moaref

Position

Resident of Neurology

Other areas of specialty/work

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Person responsible for scientific inquiries

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Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Masomeh Moaref

Position

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Other areas of specialty/work

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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