Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Nov 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
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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 leukoencephalophaty

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
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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