Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

The evaluation of the efficacy and safety of oral fingolimod in relapsing remitting multiple sclerosis

Protocol summary

Summary

In order to investigate efficacy and safety of oral fingolimod in relapsing-remitting multiple sclerosis (RRMS), a clinical trial will be done for 3 months. Participants will be recruited from RRMS patients living in Kermanshah province, referred to Emam Raza hospital MS clinic in Kermanshah, who are eligible to the study inclusion and exclusion criteria, until study sample size of 60 cases is reached. After describing study goals to the patients and providing written informed consent, patients will be admitted to hospital for at least 6 hours to receive first dose oral fingolimod (0.5 mg fingolid ® capsules,Osve pharmaceuticals) to rule out probable bradycardia and heart block. During admission heart rate, blood pressure and electrocardiogram will be monitored. Afterward patients will receive fingolimod capsules at home, once daily orally at least for 12 months. Patients will be visited at 2 weeks, 1 month, 2month, 3 month, 9 month and 12 month after intervention. In each visit patients will be investigated for MS relapse, drug complication and safety and heart rate and blood pressure will be recorded. In order to investigate disease progression, expanded disability scale score (EDSS) will be recorded every 3 months.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201406018323N10**
Registration date: **2015-01-03, 1393/10/13**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-01-03, 1393/10/13

Registrant information

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Nazanin Razazian
Name of organization / entity
Neurology Department of Kermanshah Faculty of Medicine
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Recruitment status

Recruitment complete

Funding source

kermanshah university of medicine

Expected recruitment start date

2014-12-22, 1393/10/01

Expected recruitment end date

2016-02-20, 1394/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The evaluation of the efficacy and safety of oral fingolimod in relapsing remitting multiple sclerosis

Public title

The evaluation of the efficacy and safety of oral fingolimod in relapsing remitting multiple sclerosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1.Patients with Relapsing- Remitting Multiple Sclerosis (RRMS) based on McDonald's Criteria (2010) 2.age between 18 to 45 years 3. EDSS between 0

to 5.5 4. at least one relapse in previous year while receiving first line disease modifying therapy 5.at least 2 relapses in previous 2 years while receiving first line disease modifying therapy 6. no relapses in 30 days previous to fingolimod initiation 7. negative pregnancy tests in child bearing women 8. positive history of varicella zoster virus vaccination or positive anti varicella zoster antibody in serum Exclusion criteria: 1. primary or secondary progressive MS 2. history of chronic systemic disease other than MS (lung, liver, kidney,...disease) 3. history of or active malignancy 4. presence of macular edema at baseline 5. acute or chronic active bacterial, viral or fungal infection 6. treatment with IV corticosteroids during 30 days previous to fingolimod initiation 7. history of treatment with cyclophosphamide or mitoxantrone at any time 8. history of treatment with immunoglobulins or monclonal antibodys in previous 6 months 9. history of treatment with methotroxate or azathioprine in previous 6 months 10. pregnancy or lactation 11. inocculation of live attenuated vaccines in previous 2 months 12. history of unstable angina, MI, TIA or CVA in previous 6 months 13. history of hospitalization due to decompensated heart failure in previous 6 months 14. Canada heart association class 3 or 4 heart failure 15. history or presence of second degree mobitz type AV block, third degree AV block or sick sinus syndrome, except having functional cardiac pace maker 16. QT interval more than 500 millisecond on baseline EKG 17. treatment with antiarythmic drugs class 1a or class 3 18. AST or ALT two folds normal upper limit 19. ALP 1.5 folds normal upper limit 20. direct or total Billi more than normal upper limit 21. creatinin more than 1.7 mg/dl 22. WBC less than 3500/ mm3 23. lymphocyte count less than 800/ mm3 24. presence of uveitis

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

Gender
Both

Phase
4

Groups that have been masked
No information

Sample size
Target sample size: **60**

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
Kermanshah University of Medical Sciences

Street address
Kermanshah University of Medical Sciences, Shahid Beheshti boulvered, Kermanshah

City
Kermanshah

Postal code

Approval date
2014-11-11, 1393/08/20

Ethics committee reference number
35220

Health conditions studied

1

Description of health condition studied
multiple sclerosis

ICD-10 code
G35

ICD-10 code description
Disseminated Multiple Sclerosis

Primary outcomes

1

Description
expanded disability score scale,EDSS

Timepoint
before intervention and every 3 months after intervention

Method of measurement
EDSS qustionair

Secondary outcomes

1

Description
annual relapse rate

Timepoint
before intervention and monthly after intervention

Method of measurement
physical examination by neurologist and EDSS questionair

2

Description
disability progression

Timepoint
before intervention and monthly after intervention

Method of measurement
one point increment in EDSS that remains for 3 months,

without new relapse at the time of evaluation

3

Description
drug side effects
Timepoint
before intervention and monthly after intervention
Method of measurement
patient reported complications and designed drug side effect questionair

Intervention groups

1

Description
fingolimod capsule, chemical formulation FTY -720 , (0.5 mg/ day, oral , every day) for 12 months ,made in Osvah Pharmaceutical Company in Islamic Republic Of Iran, generic name Cap. Fingolide®
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Reza Hospital of Kermanshah
Full name of responsible person
Dr. Nazanin Razazian
Street address
Emam Reza Hospital, Parastar bulvard, Sorkhelijeh, Kermanshah
City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-chancellor for research, Kermanshah University of Medical Sciences
Full name of responsible person
Mr. Shirzadian
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Kermanshah University of Medical Sciences, building no.2, Shahid Beheshti boulvered, Kermanshah
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
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Person responsible for updating data

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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