

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Safety and efficacy of fingolimod in Iranian patients with relapsing-remitting multiple sclerosis compared to interferons

Protocol summary

Study aim

Evaluation of the effect of fingolimod in relapsing-remitting multiple sclerosis compared to interferons

Design

"before and after" clinical trial without blinding
performed on 50 patients with 1 year of follow-up

Settings and conduct

In this clinical trial, 50 patients with relapsing-remitting multiple sclerosis who were qualified based on inclusion and exclusion criteria were chosen. Patients received oral fingolimod for 12 months. Relapses within 1 year prior to study was recorded. Before initiation of therapy and 12 months after initiation of intervention, MRI scan was performed and expanded disability status scale(EDSS) was calculated. During treatment course, relapses(attacks) were assessed. During study, blood lymphocyte levels, liver enzymes were evaluated. The patients were monitored for side effects, macular edema, skin lesions and cardiac arrhythmia. This study did not have blinding and it was performed in a tertiary hospital center in Mashhad which is a referral center for multiple sclerosis.

Participants/Inclusion and exclusion criteria

inclusion criteria: age 18-50, patients with relapsing remitting multiple sclerosis, no response to first line therapies
exclusion criteria: severe systemic disease, varicella infection

Intervention groups

Intervention group: Daily use of 0.5 mg oral "Fingolimod" for 12 months. It is produced in Iran by "Osve" company with brand name of "fingolid". Chemical structure of fingolimod is 2-amino-2-[2-(4-octylphenyl)ethyl]propane-1,3-diol(C₁₉H₃₃NO₂).

Main outcome variables

Number of attacks; MRI(magnetic resonance imaging) lesions, expanded disability status scale(EDSS), lymphocyte count, liver enzymes(alanine aminotransferase and aspartate aminotransferase)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170604034325N1**

Registration date: **2018-11-29, 1397/09/08**

Registration timing: **retrospective**

Last update: **2018-11-29, 1397/09/08**

Update count: **0**

Registration date

2018-11-29, 1397/09/08

Registrant information

Name

Fatemeh Yavari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3882 3103

Email address

mana_baba_110@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2014-11-22, 1393/09/01

Expected recruitment end date

2017-02-19, 1395/12/01

Actual recruitment start date

2014-11-22, 1393/09/01

Actual recruitment end date

2017-02-19, 1395/12/01

Trial completion date

2018-01-10, 1396/10/20

Scientific title

Safety and efficacy of fingolimod in Iranian patients with relapsing-remitting multiple sclerosis compared to interferons

Public title

Effects of fingolimod in treatment of multiple sclerosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Relapsing remitting multiple sclerosis according to the McDonald criteria No response or complications to first line multiple sclerosis(MS) drugs Needle phobia Age between 18 - 50 Informed consent form

Exclusion criteria:

Significant systemic disease, especially heart disease Lymphopenia Other chronic immune system diseases Varicella zoster, HTLV-1 or TB infection Macular edema Malignancy

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **50**

Actual sample size reached: **37**

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

Ethics committee of Mashhad University of Medical Sciences

Street address

Mashhad University of Medical Sciences, 94 Fakori Ave, Fakori Blvd

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2015-05-23, 1394/03/02

Ethics committee reference number

IR.MUMS.fm.REC.1394.350

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

Proportion of relapse-free patients within 12 months of fingolimod therapy

Timepoint

Number of attacks before intervention and 12 months after initiation of intervention

Method of measurement

No specific measurement tool. Evaluation by a neurologist according to clinical and radiologic findings.

2

Description

T1 and T2 MRI lesions

Timepoint

MRI scan at baseline (before intervention) and 12 months after treatment with fingolimod

Method of measurement

Magnetic resonance imaging device

Secondary outcomes

1

Description

Expanded disability status scale (EDSS)

Timepoint

At baseline (before intervention) and 12 months after initiation of fingolimod therapy

Method of measurement

Expanded disability status scale test

2

Description

Blood lymphocyte count

Timepoint

At baseline (before intervention) and at months 1,3,6 and 12 after initiation of fingolimod therapy

Method of measurement

Blood sampling-measurement using cell count device

3

Description

Aspartate aminotransferase

Timepoint

At baseline (before intervention) and at months 1,3,6 and 12 after initiation of fingolimod therapy

Method of measurement

Blood sampling. Measurement using biochemistry auto-analyzer device

4

Description

Alanine aminotransferase

Timepoint

At baseline (before intervention) and at months 1,3,6 and 12 after initiation of fingolimod therapy

Method of measurement

Blood sampling. Measurement using biochemistry auto-analyzer device

Intervention groups

1

Description

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Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Quaem hospital of Mashhad University of Medical Science

Full name of responsible person

Morteza Saeidi

Street address

Quaem hospital, Ahmad abad street, Dr. Ali Shariati square.

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Quaem.Medical.Center@mums.ac.ir

Web page address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

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Email

tafaghodim@mums.ac.ir

Web page address

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Fatemeh Yavari

Position

Neurologist

Latest degree

Medical doctor

Other areas of specialty/work

Neurology

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Morteza Saeidi

Position

Associated Professor

Latest degree

Specialist

Other areas of specialty/work

Neurology

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Person responsible for updating data

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Full name of responsible person

Fatemeh Yavari

Position

Neurologist

Latest degree

Specialist

Other areas of specialty/work

Neurology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

All data

When the data will become available and for how long

Starting 6 months after publication

To whom data/document is available

All people

Under which criteria data/document could be used

Scientific use after coordination with the researcher

From where data/document is obtainable

with e.mail : mana_baba_110@yahoo.com
meisam.radfar@gmail.com

What processes are involved for a request to access data/document

If agreed in less than a month

Comments