Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 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 cardian arrhythmia. This study did not have blinding and it was performed in a tertiary hospital center in Mashhad which is a refferal 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 findolimod 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
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 findolimod is 2-amino-2-[2-(4 octylphenyl)ethyl]propane-1,3-diol(C19H33NO2).
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.
City
Mashhad
Province
Razavi Khorasan
Postal code
99199-91766
Phone
+98 51 3840 0000
Fax
+98 51 3845 3239
Email
Quaem.Medical.Center@mums.ac.ir
Web page address
http://quaem.mums.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghodi
Street address
Mashhad University of Medical Science, Fakori Blvd
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Phone
+98 51 3841 2081
Fax
+98 51 3841 3006
Email
tafaghodim@mums.ac.ir
Web page address
http://www.mums.ac.ir/
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
Street address
No. 3, 5 Faraz street, 45 Fakori Ave, 44 Hashemie Blvd., Mashhad.
City
Mashhad

Province
Razavi Khorasan
Postal code
9177195157
Phone
+98 51 3882 3103
Fax
+98 51 3882 3103
Email
mana_baba_110@yahoo.com
Web page address
http://www.mums.ac.ir/

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
Street address
Mashhad University of Medical Science, 94 Fakori Ave, Fakoori Blvd.
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Phone
+98 51 3841 2081
Fax
+98 51 3841 3006
Email
saeidim@mums.ac.ir
Web page address
http://www.mums.ac.ir/

Person responsible for updating data

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Fatemeh Yavari
Position
Neurologist
Latest degree
Specialist
Other areas of specialty/work
Neurology
Street address
No. 3, 5 Faraz street, 45 Fakori Ave, 44 Hashemie Blvd., Mashhad.
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+98 51 3882 3103
Email
mana_baba_110@yahoo.com
Web page address
http://www.mums.ac.ir/

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