Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

Randomized, open labeled, multicenter study evaluating safety Fingolide® in patients with Relapsing- Remitting Multiple Sclerosis

Protocol summary

Summary

The aim of this study is the assessment of evaluating safety Fingolide® in patients with Relapsing- Remitting Multiple Sclerosis, over a 12 months period. Relapsing-Remitting Multiple Sclerosis patients aged between 18-50 years and Expanded Disability Status Score (EDSS) between 0-5.5 will be included. This study will be undertaken in 11 centers in Iran by presentation of 309 patients. Subjects who fulfill the eligibility criteria will be receive an oral capsule Fingolimod0.5 mg per day (made in Osvah Pharmaceutical Company). Study drug will be given orally at the first day in specialized center under supervision of a trained physician and nurse and the patient will be observed for at least 6 hours before discharge. The patient will receive the drug for the next two weeks and will be trained to use the drug for the rest of study. Subsequent dose will be taken at home. The patient will be visited every two weeks for the first month and then every month for the next 3 months and then every two months for eight months. In each visit adverse events, relapse rates and EDSS score will be recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201112267419N4**
Registration date: **2012-09-07, 1391/06/17**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-09-07, 1391/06/17

Registrant information

Name

Naghmeh Hadidi

Name of organization / entity

Osvah pharmaceutical company

Country

Iran (Islamic Republic of)

Phone

+98 21 2213 1066

Email address

n.hadidi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Osvah Pharmaceutical Company , Tehran University of Medical Sciences

Expected recruitment start date

2012-08-21, 1391/05/31

Expected recruitment end date

2013-08-22, 1392/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Randomized, open labeled, multicenter study evaluating safety Fingolide® in patients with Relapsing- Remitting Multiple Sclerosis

Public title

Randomized, open labeled, multicenter study evaluating safety Fingolide® in patients with Relapsing- Remitting Multiple Sclerosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: 1.Patients with Relapsing- Remitting Multiple Sclerosis (MS) based on McDonald's Criteria (2010) 2. Age between 18-50 years old 3.Expanded Disability Status Scale (EDSS) 0- 5.5 4. Negative

pregnancy test at baseline 5.Signing consent form 6. History of Chicken pox, VZV vaccination or positive antibody. 7. At least one documented relapse during one year prior to study while on first line disease modifying therapies. 8. No relapse during the last 30 days. Exclusion Criteria : 1.Secondry or primary progressive MS 2.History of a chronic disease other than MS 3. History or presence of malignancy 4. Macular edema at onset 5. Active bacterial, fungal or viral infection 6. Treatment with corticosteorids (IV) during the past 30 days 7. Patients who have been previously treated with cyclophosphamide and mitoxantrone 8.Patients who have been treated with immunoglubulins or monoclonal antibodies during the past six months 9. Patients who have been treated with azothioprine or methtroxate during the past six months 10. Patients who have been treated with beta- Interferon or GA during the past 3 months 11.Medically Unstable patient according to site physician 12. Patient with history of syncope 13. History of cardiac arrest, heart failure, recurrent symptomatic bradycardia or ischemic heart disease 14. Abnormal Electro Cardio Gram (ECG) (Block, QT interval more than 440 milliseconds on screening ECG 15. Hypertension not controlled by prescribed medications 16.Patients with severe respiratory disease, Active pulmonary disease, Tuberculosis except successful treatment or prophylactic treatment after positive purified protein derivative (PPD) 17. Lost to follow up more than 3 months

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
4

Groups that have been masked
No information

Sample size
Target sample size: **309**

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
Tehran University of Medical Sciences Ethics Committee

Street address
Vice chancellor for research ,Tehran University of Medical Sciences, Qods Street , Keshavarz Boulevard .

City
Tehran

Postal code
-

Approval date
2013-02-19, 1391/12/01

Ethics committee reference number
-

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
Relapse Rate

Timepoint
Before intervention and every month after intervention

Method of measurement
Physical examination done by neurologist and Expanded Disability Status Scale (EDSS)

Secondary outcomes

1

Description
Expanded Disability Status Scale

Timepoint
Before intervention and every month after intervention

Method of measurement
Physical examination done by neurologist based on revised Mc-Donald (2010)

2

Description
Number and size of plaques and their enhancement

Timepoint
Before intervention and every six months after intervention

Method of measurement
Magnetic resonance Imaging (MRI)

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
Sina Hospital
Full name of responsible person
Dr. Mohammad Ali Sahraian
Street address
Sina Hospital,before Hasan abad Square , Imam Khomeini Street
City
Tehran

2

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Dr. Mohammad Hossein Harirchian
Street address
The end of Keshavarz Boulevard , Vali Asr Square , Tehran
City
Tehran

3

Recruitment center
Name of recruitment center
Loghman Hakim Hospital
Full name of responsible person
Dr. Hosein Pakdaman
Street address
Makhsoos Street , Qazvin Square , South Karegar Avenue , Tehran
City
Tehran

4

Recruitment center
Name of recruitment center
Imam Hossein Hospital
Full name of responsible person
Dr.Nahid Beladi Moghaddam
Street address
Madani Avenue , Tehran
City
Tehran

5

Recruitment center
Name of recruitment center
Alzahra Hospital
Full name of responsible person
Dr. Masoud Etemadifar
Street address
Safeh Boulevard ,Aghareb Parast Avenue , Isfahan
City
Isfahan

6

Recruitment center
Name of recruitment center
Ayatollah Kashani Hospital
Full name of responsible person
Dr. Vahid Shaygannejad
Street address
Kashani Street , Isfahan
City
Isfahan

7

Recruitment center
Name of recruitment center
Namazi Hospital
Full name of responsible person
Dr. Ali Reza Nikseresht
Street address
Namazi Square, Shiraz
City
Shiraz

8

Recruitment center
Name of recruitment center
Ghaem Hospital
Full name of responsible person
Dr. Mohsen Foroughipour
Street address
Ahmadabad Avenue, Dr. shariati Square, Mashhad
City
Mashhad

9

Recruitment center
Name of recruitment center
Golestan Hospital
Full name of responsible person
Dr. Nastaran Majdi nasab
Street address
Golestan Ahwaz
City
Ahwaz

10

Recruitment center
Name of recruitment center

Shafa Hospital

Full name of responsible person

Dr. behnaz sedighi

Street address

Farabi Stree , Kerman

City

Kerman

11

Recruitment center

Name of recruitment center

Imam Reza Hopital

Full name of responsible person

Dr. Hormoz Ayromlou

Street address

Golgasht Street , Tabriz

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Osvah Pharmaceutical Company

Full name of responsible person

Dr. Abbas Kebriaee zadeh

Street address

5th floor - Number112 - Western Hafezi street - Farahzadi Avenue - Shahrake gharb

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Osvah Pharmaceutical Company

Proportion provided by this source

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

2

Sponsor

Name of organization / entity

Vice chancellor for research ,Tehran University of Medical Sciences

Full name of responsible person

-

Street address

Vice chancellor for research ,Tehran University of Medical Sciences, Qods Street, Keshavarz Boulevard.

City

Tehran

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 ,Tehran University of Medical Sciences

Proportion provided by this source

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

Osvah Pharmaceutical Company

Full name of responsible person

Dr. Naghmeh Hadidi

Position

PhD Graduate of Pharmaceutics /The head of market researches and clinical trials department

Other areas of specialty/work

Street address

5th floor - Number 112 - Western Hafezi street - Farahzadi Avenue - Shahrake gharb

City

Tehran

Postal code

-

Phone

+98 21 2213 1066

Fax

-

Email

hadidi@gmail.com

Web page address

-

Person responsible for scientific inquiries

Contact

Name of organization / entity

Sina Hospital

Full name of responsible person

Dr. Mohammad Ali Sahraian

Position

Neurologist-MS Fellowship/Associate Professor

Other areas of specialty/work

Street address
Sina Hospital, before Hasan abad Square , Imam Khomeini Street.
City
Tehran
Postal code
-
Phone
+98 21 6634 8571
Fax
+98 21 6634 8570
Email
msahrai@sina.tums.ac.ir
Web page address
-

Person responsible for updating data

Contact
Name of organization / entity
Osvah Pharmaceutical Company
Full name of responsible person
Dr. Naghmeh Hadidi
Position
PhD Graduate of Pharmaceutics /The head of market researches and clinical trials department
Other areas of specialty/work
Street address
5th floor- Number112- Western Hafezi street - Farahzadi Avenue - Shahrake gharb
City
Tehran
Postal code
-
Phone
+98 21 2213 1066
Fax
-
Email
hadidi@gmail.com n.hadidi@sbmu.ac.ir
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