

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Sep 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 Fingolimod 0.5 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. Secondary 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 corticosteroids (IV) during the past 30 days 7. Patients who have been previously treated with cyclophosphamide and mitoxantrone 8. Patients who have been treated with immunoglobulins or monoclonal antibodies during the past six months 9. Patients who have been treated with azathioprine or methotrexate 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
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11

Recruitment center

Name of recruitment center
Imam Reza Hopital
Full name of responsible person
Dr. Hormoz Ayromlou
Street address
Golgasht Street , Tabriz
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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
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Person responsible for scientific inquiries

Contact

Name of organization / entity
Sina Hospital
Full name of responsible person
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Position
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Web page address

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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 -

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