Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

comparison of the effect of Fingolimode and Betaferon (high dose) in decreasing the symptoms and relapse rates of MS patients whose treatment with Betaferon (low dose) was failed.

Protocol summary

Summary

This is a randomized blind clinical trial for comparing oral drug (Fingolimode) with high dose interferone (S.C) in treating symptoms and reduction of relapse rates in MS patients.50 patients with inclusion criteria who were under treatment of low dose Betaferon (Cinnovex.Avonex.Actovex) and have treatment failure. (more than one relapse during one year) will categorize in two randomized selected groups .we prescribe Fingolimode in 0.5 mg daily for first group and Betaferon (high dose) (Rebif.Actorif.Recigen) in second one through S.C every three days .patients will be evaluated through months 0.3.9.12.18 (5 visits after intervention) by neurologist who will not interfer in any parts of study and will not be aware of which patients will take which treatment. patients will analysis through E.D.S.S for surveying the intensity of disease or relapses.MRI will also be take through months 0 and 18.at last data will be analysed.

General information

Acronym
E.D.S.S

IRCT registration information
IRCT registration number: **IRCT2015112025146N1**
Registration date: **2016-02-18, 1394/11/29**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date
2016-02-18, 1394/11/29

Registrant information

Name
Pedram Moeini

Name of organization / entity
Isfahan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source
Isfahan University of Medical Sciences

Expected recruitment start date
2014-10-27, 1393/08/05

Expected recruitment end date
2015-04-19, 1394/01/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
comparison of the effect of Fingolimode and Betaferon (high dose) in decreasing the symptoms and relapse rates of MS patients whose treatment with Betaferon (low dose) was failed.

Public title
comparison of Fingolimode and Betaferon(high dose) in M.S treatment

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:The most important one is MS patients who had treatment failure (relapsing rate more than one) under Betaferon (low dose) ; patient acceptance; non

immunosuppressive patient. Exclusion criteria: noncooperative patient; death

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Commitee of Isfahan University of Medical Sciences

Street address
Hezar jarib street, Darvazeshiraz square

City
Isfahan

Postal code

Approval date
2015-01-22, 1393/11/02

Ethics committee reference number
394053

Health conditions studied

1

Description of health condition studied
M.S

ICD-10 code
G35

ICD-10 code description
Multiple Sclerosis

Primary outcomes

1

Description
Disability Status

Timepoint
befor intervention and 3.9.12.18 months after intervention

Method of measurement
Check list of E.D.S.S

2

Description
Relapse Numbers

Timepoint
0,3,9,12,18 months after intervention

Method of measurement
History and observation

Secondary outcomes

empty

Intervention groups

1

Description
Fingolimode 0.5 mg /day will orally prescribe 18 months for a subgroup of patients who had treatment failure with Betaferon (low dose) during last year.

Category
Treatment - Drugs

2

Description
Betaferon high dose s.c every 2 days will prescribe 18 months for the other subgroup of patients who had treatment failure during last year with Betaferon (low dose).

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
St ZAHRA Hospital

Full name of responsible person
Pedram Moeini

Street address
Sofhe street, Hakim nezami Street

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Isfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Isfahan University of Medical Sciences
Full name of responsible person
Dr.Mehdi Nematbakhsh
Street address
Hezar jarib street, Darvazeshiraz square
City
Isfahan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Isfahan 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

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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