Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The therapeutic effect of Avonex, Rebif and Betaferon on disability and quality of life in multiple sclerosis: A Randomized Clinical Trial

Protocol summary

Summary

Purpose: To evaluate the effect of various disease-modifying therapies (DMTs) on quality of life in multiple sclerosis (MS). Design: Three-arm parallel study with balanced randomization. Participants: Ninety newly diagnosed, definite MS subjects referred to Ghaem Medical Center, Mashhad, Iran were enrolled into this study between 2006 and 2009. Method: Patients were randomly allocated into three DMT groups; Avonex, Rebif and Betaferon. Health-related quality of life was assessed in MS patients at baseline and 12 months after treatment with DMTs using the MSQOL-54 questionnaire. Patients were excluded if they had history of substance abuse, treatment with any other type of DMTs or had any signs of depression using semi-structural psychiatric interviews as well as the Beck Depression Inventory. Treatment protocol Patients were randomly assigned using a computer-generated list of random numbers to receive three distinct commercially available forms of interferon beta; Avonex, Rebif, and Betaferon. Avonex was administered 30mcg once per week via intramuscular injection. Rebif was administered 44mcg three times per week via subcutaneous injection. Betaferon was administered 0.25mg every other day via subcutaneous injection. Patients (or their caregivers) were trained by the study neurologist (MRA) to self-administer their assigned medication.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201404195280N16**
Registration date: **2014-04-26, 1393/02/06**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-04-26, 1393/02/06

Registrant information

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Name of organization / entity
Mashhad University of Medical Scinces, Ibn-e- Sina Psychiatric Hospital
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Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2006-07-23, 1385/05/01

Expected recruitment end date

2009-07-23, 1388/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The therapeutic effect of Avonex, Rebif and Betaferon on disability and quality of life in multiple sclerosis: A Randomized Clinical Trial

Public title

The therapeutic effect of Avonex, Rebif and Betaferon on disability and quality of life in multiple sclerosis: A Randomized Clinical Trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: newly diagnosed MS subjects. Exclution criteria: had history of substance abuse;treatment with any other type of DMTs ; had any signs of depression.

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mashhad University of Medical Sciences

Street address

Ghoreish building, Daneshgah Street.

City

Mashhad

Postal code

Approval date

2006-07-19, 1385/04/28

Ethics committee reference number

84394

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

disability

Timepoint

baseline and 12 months after treatment

Method of measurement

The expanded disability status scale (EDSS)

2

Description

quality of life

Timepoint

baseline and 12 months after treatment

Method of measurement

MSQOL-54 questionnaire.

Secondary outcomes

empty

Intervention groups

1

Description

Avonex was administered 30mcg once per week via intramuscular injection

Category

Treatment - Drugs

2

Description

Rebif was administered 44mcg three times per week via subcutaneous injection

Category

Treatment - Drugs

3

Description

Betaferon was administered 0.25mg every other day via subcutaneous injection.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem Hospital

Full name of responsible person

Street address

City

Mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Ardakanian Marjan
Street address
Ghoreish building, Daneshgah street.
City
Mashhad
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
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
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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