Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

A Randomized, Double-blind Controlled Study to Determine the Effectiveness, Safety and Tolerability of Actoferon® Compared to Betaferon® in Subjects with Relapsing Remitting Multiple Sclerosis (RRMS)

Protocol summary

Summary
The Trial is performed in aKheradmand research center on 2 groups of 70 patients with RRMS who will be chosen based on inclusion and exclusion criteria and randomization that will allocate two different types of of INF-β-1b, Actoferon and Betaferon to our patients. The occurrence of side effects, Tolerability and clinical efficiency will be assessed by evaluating patients on definite times during treatment which takes 12 month.

General information

Acronym
IRCT registration information
IRCT registration number: **IRCT2013030512398N2**
Registration date: **2014-03-04, 1392/12/13**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date
2014-03-04, 1392/12/13

Registrant information

Name
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Actover Pharmaceutical Company
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Recruitment status
Recruitment complete
Funding source
Actover Pharmaceutical Company

Expected recruitment start date
2011-10-20, 1390/07/28
Expected recruitment end date
2015-07-21, 1394/04/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A Randomized, Double-blind Controlled Study to Determine the Effectiveness, Safety and Tolerability of Actoferon® Compared to Betaferon® in Subjects with Relapsing Remitting Multiple Sclerosis (RRMS)

Public title
The Effectiveness, Safety and Tolerability of Actoferon® Compared to Betaferon® in Subjects with Relapsing Remitting Multiple Sclerosis (RRMS)
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion Criteria: Male or female patients aged between 18-55 years, with a diagnosis of RRMS based on McDonald criteria 2010and or have two relapses in previous two years, and are eligible for interferon beta 1b therapy according to indications and clinical use in the product monograph; Patients must have an EDSS score of 0.0 to 5.5;Patients must have at least 2 relapses in previous 2 years; Signed informed consent obtained prior to initiation the study; Patients do not have any condition that mandates excluding them from the study;

Female patients of child-bearing potential must have a negative pregnancy test and use at least one form of contraception as approved by the Investigator for four weeks prior to the study and during the study. For the purposes of this study, child-bearing potential is defined as: “All female patients unless they are post-menopausal for at least one year or are surgically sterile”; Ability to co-operate with the treatment and follow up. Exclusion Criteria Disease-dependent criteria(Participant has an ongoing MS relapse; Has any progressive form of MS;Presenting MS relapse within 30 days prior to study drug administration); Safety of treatment dependent criteria: Presence of any serious concomitant systemic disorders incompatible with the administration of interferon beta-1b or any systemic disease that can influence the patient's safety(history of hypersensitivity to natural or recombinant interferon beta-1b, or hypersensitivity to human albumin or any other component of the formulation; History of uncontrolled seizures within the 3 months prior to enrollment; History of suicidal ideation or an episode of severe depression within the 3 months prior to enrollment; Serious local infection or systemic infection within 8 weeks prior to enrollment; Pregnant or breast-feeding patients or any patient with childbearing potential not using adequate contraception; History of major depression; History of major cardiac disease; History of known malignancy(except: S.C.C,B.C.C, non melanoma) or patient who is under chemotherapy); Patients with inadequate organ function(Bone Marrow: absolute neutrophil count (ANC) ≤ 1.5 x 109/L, platelet count ≤100 x 109/L,Hemoglobin ≤ 9 g/dL; Hepatic: Bilirubin ≥ 1.5 x the upper limit of normal (ULN),aspartate transaminases (AST/SGOT) And/or alkaline transaminases(ALT/SGPT)≥2.5xULN,alkaline phosphatase (AP)≥2.5 x ULN; Renal: Serum creatinine ≥1.5 mg/dL or creatinine clearance ≤ 60 mL/min calculated according to the Cockroft and Gault formula); Criteria dependent on compliance with study procedures, or the evaluation of the disability(Unwilling to use a reliable and acceptable contraceptive method throughout the study period;Conditions interfering with Magnetic Resonance Imaging (MRI) or Gadolinium DTPA (Gadovist, contrast agent) allergy or Inability to undergo MRI with gadolinium administration;Treatment with certain other agents to treat MS underlying disease; Participant received any other approved disease modifying therapy for MS (e.g. glatiramer acetate IV, Immunoglobulin, Azathriopine, Methotrexate, Cyclophosphamide, Mitoxantrona, Plasmapheresis) or any cytokine or anti-cytokine therapy within the 3 months prior to Study Day 0 (SD0);Systemic corticosteroids within 30 days prior to the initiation of this study treatment;Treatment with any investigational product within 30 days prior to study drug administration; Previous participation in this study)

Age
From **18 years** old to **55 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **140**

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
Vice chancellor for research, Shahid Beheshti University of Medical Sciences,Neurology Department

Street address
Beside the Taleghani hospital,Chamran highway,
Tehran, Iran

City
Tehran

Postal code

Approval date
2012-12-18, 1391/09/28

Ethics committee reference number
400.8871

Health conditions studied

1

Description of health condition studied
Comparative interventional IFN.β-1b treatment in Relapsing Remitting Multiple Sclerosis (RRMS)

ICD-10 code
G35

ICD-10 code description
Multiple Sclerosis

Primary outcomes

1

Description
Safety outcome :Prevalence of Flu like Syndrome

Timepoint
At 6th, 12th after initial treatment

Method of measurement
The Frequency of Flu like syndrome

2

Description
Tolerability outcome: The prevalence of Heacache
Timepoint
At 6th,12th months after initial treatment
Method of measurement
The Frequency of headache

3

Description
Effectiveness outcome: The proportion of Relapse
Timepoint
At 6th,12th months after initial treatment
Method of measurement
The frequency of relapse (Clinical,MRI)

Secondary outcomes

1

Description
Effectiveness outcome: Proportion of progression
Timepoint
At 3th, 6th,12th months after initial treatment
Method of measurement
The frequency of progression(Clinical,EDSS, MRI)

2

Description
Safety outcome: Prevalence of Injection site reaction
Timepoint
At 6th,12th months after initial treatment
Method of measurement
The frequency of injection site reaction

3

Description
Safety outcome: Prevalence of Laboratory abnormalities
Timepoint
At 6th,12th months after initial treatment
Method of measurement
The frequency laboratory abnormalities(LFT,leukopenia)

4

Description
Tolerability outcome: The prevalence of AEs
Timepoint
At 6th,12th months after initial treatment
Method of measurement
The frequency of AEs(Vomiting,Nausea)

Intervention groups

1

Description
Group A (Intervention): They get Actoferon(Interferon beta-1b) 300 mcg as lyophilized powder in vials and solvent in prefilled syringes, Supplied by Actover/Gemabiotech. It will be administered 3 times a week subcutaneously
Category
Treatment - Drugs

2

Description
Group B (Control) : They get Betaferon(Interferon beta-1b) 250mcg as lyophilized powder in vials and solvent in prefilled syringes Supplied by Bayer-Schering Pharma. It will be administered 3 times a week subcutaneously.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Kheradmand Research Center
Full name of responsible person
Dr Ali Etemadrezaee
Street address
Unit 15,No.47,South Kheradmand Ave, Karim khan Zand St,Tehran,Iran
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Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Actover Pharmaceutical company
Full name of responsible person
Nahaleh Naraghii (MSC)
Street address
No.17, Dashte Behesht Ave,Saadat abad Ave,Tehran,Iran
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Actover Pharmaceutical company
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
Name of organization / entity
Actover Pharmaceutical Company
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Farhad Hatami Sadabadi (MD)
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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