

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Sep 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 INF- $\beta$ -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

Farhad Hatami Sadabadi

###### Name of organization / entity

Actover Pharmaceutical Company

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2206 1704

###### Email address

farhad.hatami@actoverco.com

##### 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 2010 and 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;

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| <p>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) <math>\leq 1.5 \times 10^9/L</math>, platelet count <math>\leq 100 \times 10^9/L</math>, Hemoglobin <math>\leq 9</math> g/dL; Hepatic: Bilirubin <math>\geq 1.5 \times</math> the upper limit of normal (ULN), aspartate transaminases (AST/SGOT) And/or alkaline transaminases(ALT/SGPT)<math>\geq 2.5 \times</math>ULN, alkaline phosphatase (AP)<math>\geq 2.5 \times</math> ULN; Renal: Serum creatinine <math>\geq 1.5</math> mg/dL or creatinine clearance <math>\leq 60</math> mL/min calculated according to the Cockcroft 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, Azathioprine, Methotrexate, Cyclophosphamide, Mitoxantrone, 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)</p> <p><b>Age</b><br/>From <b>18 years</b> old to <b>55 years</b> old</p> <p><b>Gender</b><br/>Both</p> <p><b>Phase</b><br/>3</p> <p><b>Groups that have been masked</b></p> | <p><i>No information</i></p> <p><b>Sample size</b><br/>Target sample size: <b>140</b></p> <p><b>Randomization (investigator's opinion)</b><br/>Randomized</p> <p><b>Randomization description</b></p> <p><b>Blinding (investigator's opinion)</b><br/>Double blinded</p> <p><b>Blinding description</b></p> <p><b>Placebo</b><br/>Not used</p> <p><b>Assignment</b><br/>Parallel</p> <p><b>Other design features</b></p> <p><b>Secondary Ids</b><br/>empty</p> <p><b>Ethics committees</b></p> <p><b>1</b></p> <p><b>Ethics committee</b></p> <p><b>Name of ethics committee</b><br/>Vice chancellor for research, Shahid Beheshti University of Medical Sciences,Neurology Department</p> <p><b>Street address</b><br/>Beside the Taleghani hospital,Chamran highway, Tehran, Iran</p> <p><b>City</b><br/>Tehran</p> <p><b>Postal code</b></p> <p><b>Approval date</b><br/>2012-12-18, 1391/09/28</p> <p><b>Ethics committee reference number</b><br/>400.8871</p> <p><b>Health conditions studied</b></p> <p><b>1</b></p> <p><b>Description of health condition studied</b><br/>Comparative interventional IFN.<math>\beta</math>-1b treatment in Relapsing Remitting Multiple Sclerosis (RRMS)</p> <p><b>ICD-10 code</b><br/>G35</p> <p><b>ICD-10 code description</b><br/>Multiple Sclerosis</p> <p><b>Primary outcomes</b></p> <p><b>1</b></p> <p><b>Description</b><br/>Safety outcome :Prevalence of Flu like Syndrome</p> <p><b>Timepoint</b><br/>At 6th, 12th after initial treatment</p> <p><b>Method of measurement</b><br/>The Frequency of Flu like syndrome</p> |
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## 2

### **Description**

Tolerability outcome: The prevalence of Headache

### **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

#### **City**

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

**Full name of responsible person**

Farhad Hatami Sadabadi (MD)

**Position**

Clinical trial manager

**Other areas of specialty/work**

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+98 21 2206 9696

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**Email**

Farhad.hatami@actoverco.com

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences,  
Neurology Dep.

**Full name of responsible person**

Kurosh Gharagozli (MD)

**Position**

Principal Investigator/ Neurologist, Associate  
Professor

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Actover Pharmaceutical Company

**Full name of responsible person**

Farhad Hatami Sadabadi (MD)

**Position**

Monitor / MD

**Other areas of specialty/work**

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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*