

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

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

Protocol summary

Summary

The Trial is performed in a research center on 2 groups of 72 patients with RRMS who will be chosen based on inclusion and exclusion criteria and randomization that will allocate two different types of INF-β-1a, Actorif and Rebif 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: **IRCT2013030512398N3**

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

Biosun Pharmed Pharmaceutical Company

Expected recruitment start date

2011-10-21, 1390/07/29

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 Actorif® Compared to Rebif® in Subjects with Relapsing Remitting Multiple Sclerosis (RRMS)

Public title

The Effectiveness, Safety and Tolerability of Actorif® Compared to Rebif® 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 1a 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-1a or any systemic disease that can influence the patient's safety (history of hypersensitivity to natural or recombinant interferon beta-1a, 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) $\leq 1.5 \times 10^9/L$, platelet count $\leq 100 \times 10^9/L$, Hemoglobin ≤ 9 g/dL; Hepatic: Bilirubin $\geq 1.5 \times$ the upper limit of normal (ULN), aspartate transaminases (AST/SGOT) And/or alkaline transaminases (ALT/SGPT) $\geq 2.5 \times$ ULN, alkaline phosphatase (AP) $\geq 2.5 \times$ ULN; Renal: Serum creatinine ≥ 1.5 mg/dL or creatinine clearance ≤ 60 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.)

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: **144**

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 of Shahed Medical University, Neurology department

Street address

Shahed University, opposite of the Emam Khomeini Shrine, Tehran-Ghom free way, Tehran, Iran

City

Tehran

Postal code

3319118651

Approval date

2013-03-06, 1391/12/16

Ethics committee reference number

41.166347

Health conditions studied**1****Description of health condition studied**

Multiple sclerosis

ICD-10 code

G35

ICD-10 code description

Demyelinating diseases of the central nervous system

Primary outcomes**1****Description**

Safety outcome : Prevalence of Flu like Syndrome

Timepoint

At 6th, 12th months after initial treatment

Method of measurement

The Frequency of Flu like syndrome

2**Description**

Effectiveness outcome: The proportion of Relapse

Timepoint

At 6th,12th months after initial treatment

Method of measurement

The frequency of relapse (Clinical,MRI)

3

Description

Tolerability outcome: The prevalence of Heacache

Timepoint

At 6th,12th months after initial treatment

Method of measurement

The Frequency of headache

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 Actorif (Interferon beta-1a) 44mcg/0.5ml in prefilled syringes, Supplied by Actover/Amegabiotech. It will be administered 3 times a week subcutaneously.

Category

Treatment - Drugs

2

Description

Group B (Control) : They get Rebif (Interferon beta-1a) beta -1a 44mcg/0.5ml in prefilled syringes, Supplied by Merck Serono .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 Etemadrezaei

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

Biosun Pharmed Company

Full name of responsible person

Shima Kheibari

Street address

Unit 702, No.14, Golestan Alley, Aghaalikhani St., Sheikh Bahaei Ave

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Biosun Pharmed 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

Monitor / MD

Other areas of specialty/work**Street address**

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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)

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Principal Investigator ,Nurologist / Associate professor

Other areas of specialty/work**Street address**

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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