

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

The Comparison of clinical and side effects of Cinnaferon with Betaferon in patients with Relapsing- Remitting Multiple Sclerosis

Protocol summary

Summary

The aim of this study is the assessment of the efficacy and safety of Cinnaferon (Interferon beta-1- b, Subcutaneous, every other day) in patients with Relapsing- Remitting multiple sclerosis, over a 24-month period. This study will be undertaken in one center in Iran (Tehran, Sina Hospital). Relapsing-Remitting Multiple Sclerosis patients aged between 18-50 years and Expanded Disability Status Score (EDSS) between 0-5.5 will be included. These individuals are randomly divided into two groups. The intervention group receives Cinnaferon (250µgr / 8 mlU / day, subcutaneous, every other day) and the control group receives Betaferon (250µgr / 8 mlU / day, subcutaneous, every other day). To avoid any prejudgment, both patients group and physicians will not be informed about the type of prescribed medication (Cinnaferon or Betaferon) , but they will be informed about chemical formulation of the drug as beta interferon1-b. The patients in both groups will be evaluated and compared by the number of relapses, the change in EDSS score, MRI findings and neutralizing antibodies. In addition, side effects will be systematically recorded for both treatments.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201205221859N4**

Registration date: **2012-10-09, 1391/07/18**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-10-09, 1391/07/18

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

CinnaGen Pharmaceutical Company, Tehran University of Medical Sciences

Expected recruitment start date

2012-06-21, 1391/04/01

Expected recruitment end date

2012-12-21, 1391/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Comparison of clinical and side effects of Cinnaferon with Betaferon in patients with Relapsing- Remitting Multiple Sclerosis

Public title

The Comparison of effects of Cinnaferon with Betaferon in Relapsing- Remitting Multiple Sclerosis

Purpose

Treatment

Inclusion/Exclusion criteria

-Inclusion criteria: 1. Patients with Relapsing- Remitting Multiple Sclerosis based on McDonald's Criteria 2.age between 18-50 years old 3. Expanded Disability Status

Scale (EDSS) 0- 5.5 4. Negative pregnancy test at baseline 5. Patients without Relapse in one last month 6. Signing consent form. -Exclusion criteria: 1. Being pregnant during trial or intention to get pregnant in start of trial 2. Psychiatric disease or major depression 3. The history of suicide 4. Allergy or hypersensitivity reaction to injected medication in the start of trial 5. Treatment with Intravenous immunoglobulin (IVIG) within six months prior to trial 6. The history of plasma exchange within 6 months prior to trial 7. Using cytotoxic medication within six months prior to trial 8. The history of using beta interferon within three months prior to trial 9. Impaired Liver Function Tests (more than 2 times normal range) 10. Leukopenia (less than half of the normal range) 11. Other types of multiple sclerosis except relapsing-remitting type 12. Association with other autoimmune diseases 13. The history of malignancy 14. The history of chronic liver disease except Gilbert's syndrome 15. The history of renal dysfunction with creatinine (Cr) more than 1.1mg/dl 16. Patients with the history of fear from Magnetic resonance Imaging (MRI) or Claustrophobia 17. The history of sensitivity to Gadolinium (Gd) 18. Patient participation in another clinical trial at the same time 19. Breastfeeding .

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **76**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Randomization method and process: All patients fulfilling inclusion criteria - without any exclusion item - will enter one of two study arms, Cinniferon Vs. Betaferon, via a permuted block method, after they sign an informed consent letter. Permuted block method will create randomized numbers, one for each patient, in order to divide them in two complete equal arms with randomized based selection.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Tehran University of Medical Sciences Ethics Committee

Street address

Vice chancellor for research ,Tehran University of Medical Sciences, Qods St, Keshavarz Blvd.

City

Tehran

Postal code**Approval date**

2012-01-07, 1390/10/17

Ethics committee reference number

2248-130-90-ص

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

Multiple Sclerosis

ICD-10 code

G35

ICD-10 code description

Disseminated Multiple Sclerosis

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

Relapse Rate

Timepoint

Before intervention and every month after intervention

Method of measurement

Physical examination done by neurologist and EDSS

Secondary outcomes**1****Description**

EDSS Expanded Disability Status Scale

Timepoint

Before intervention and every month after intervention

Method of measurement

Physical examination done by neurologist based on revised Mc-Donald (2010)

2**Description**

Number and size of plaques and their enhancement

Timepoint

Before intervention and every six months after intervention

Method of measurement

Magnetic resonance Imaging (MRI)

3

Description

Neutralizing Antibodies

Timepoint

Before intervention and every six months after intervention

Method of measurement

measurement in peripheral blood

Intervention groups

1

Description

Amp Cinnaféron ,chemical formulation beta interferon1-b, (250µgr / 8 mIU / day, subcutaneous, every other day) for 24 months ,made in Cinnagen Pharmaceutical company in Islamic Republic Of Iran, generic name Amp Cinnaféron

Category

Treatment - Drugs

2

Description

Amp Betaferon ,chemical formulation beta interferon1-b, (250µgr / 8 mIU / day, subcutaneous , every other day)for 24 months, made in Bayer company in Germany, generic name Amp Betaferon

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Dr AmirReza Azimi

Street address

Hasan abad Sq. , Imam Khomeini St.

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Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Cinnagen Pharmaceutical Company

Full name of responsible person

Dr Shiva Salami

Street address

No. 2, 7th Alley, Simay-e-Iran St, Shahrak-e-Qods

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Cinnagen Pharmaceutical Company

Proportion provided by this source

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

2

Sponsor

Name of organization / entity

Vice chancellor for research ,Tehran University of Medical Sciences

Full name of responsible person

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City

Tehran

Grant name

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Vice chancellor for research ,Tehran University of Medical Sciences

Proportion provided by this source

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

Cinnagen Pharmaceutical Company

Full name of responsible person

Dr Shiva Salami

Position

General Physician/Clinical Research Manager

Other areas of specialty/work

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Web page address**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*