Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 mIU / day, subcutaneous, every other day) and the control group receives Betaferon (250µgr / 8 mIU / day, subcutaneous, every other day). To avoid any prejudgment, both patients group and physicians will not 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

Name

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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 suicide4. 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 2times 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, Cinnaferon 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 Cinnaferon ,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 Cinnaferon
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.
City
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
-
Street address
Vice chancellor for research ,Tehran University of Medical Sciences, Qods St, Keshavarz Blvd.
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
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
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Person responsible for scientific inquiries

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Person responsible for updating data

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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