Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparative study of the effect of Cinnagen's interferon beta and Avonex on relapsing-remitting Multiple Sclerosis

Protocol summary

Summary

Interferon betas are the main approved medication for treatment of Multiple sclerosis. A biosimilar form of Avonex called CinnoVex has been manufactured and the aim of this study is to compare safety and efficacy of CinnoVex compared to Avonex. This study is a Randomized, double-blind controlled trial in relapsing-remitting multiple sclerosis patients as defined by Mc Donald criteria. Inclusion criteria are 18-50 years old at the time of entry with EDSS≤5.5. Patients with progressive MS, pregnancy or the desire to become pregnant, major depression or major psychiatric problem, history of suicidal attempt, IVIG or cytotoxic drugs in the past 6 months, allergic reaction to β-interferon, increased liver enzymes more than 3 times or any evidence of liver dysfunction, leukopenia or patients lost for follow-up for more than 4 weeks were excluded. All eligible patients filled a written informed consent. Laboratory tests and brain MRI with standard protocol was performed at baseline. 60 Patients were randomly assigned in a 1:1 ratio to receive either CinnoVex® or Avonex® 30µg IM QW for104 weeks. Adverse events and lab tests are recorded every week for the first 4 weeks and every 4 weeks afterwards. Patients were examined monthly by a neurologist and brain MRI and NAbs was performed every 6 months. On each MRI, number of T2-plaques were counted and volumetry performed by a single blinded rater using Image J software and the number of enhancing lesions recorded. Relapses and symptoms were treated as necessary. Adverse effects were monitored by a 60-item checklist.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138711281696N1**
Registration date: **2009-07-29, 1388/05/07**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2009-07-29, 1388/05/07

Registrant information

Name

Shahriar Nafissi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8490 2224

Email address

nafisi@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Cinnagen co.

Expected recruitment start date

2006-08-20, 1385/05/29

Expected recruitment end date

2007-08-20, 1386/05/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of the effect of Cinnagen's interferon beta and Avonex on relapsing-remitting Multiple Sclerosis

Public title

Cinnovex versus Avonex clinica Trial

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion criteria:RRMS as defined by Mc Donald's criteria, Age: 18-50 years, EDSS 0-5.5, signing informed consent Exclusion Criteria: Pregnancy or the desire to become pregnant during the trial period, major depression or psychiatric problem, history of suicidal attempt, Allergy to INF-beta, IVIG during the past 6 months, Cytotoxic medications, increased liver enzymes >3 times, leucopenia, missing patient for 4 consecutive weeks, plasmapheresis.
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: **60**
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
Tehran University of Medical Sciences
Street address
Keshavarz Blvd.
City
Tehran
Postal code
Approval date
empty
Ethics committee reference number
132/6260

2

Ethics committee
Name of ethics committee
Ministry of Health
Street address
Vice-chancelor for research and technology of Ministry of Health and Medical Education, Azadi Street
City
Tehran
Postal code
Approval date
2006-10-02, 1385/07/10
Ethics committee reference number
6516

Health conditions studied

1

Description of health condition studied
Multiple Sclerosis
ICD-10 code
G35
ICD-10 code description
Multiple Sclerosis

Primary outcomes

1

Description
Disability
Timepoint
Monthly for 2 years, since one month after intervention
Method of measurement
Expanded disability status scale (EDSS)

Secondary outcomes

1

Description
Number of attacks
Timepoint
monthly for 2 years, since one month after intervention
Method of measurement
reported by the patient and detected on examination

2

Description
MRI Changes
Timepoint
Baseline and since 6 months after intervention, every 6 months for 2 years
Method of measurement
Image J software

3

Description
Neutralizing Antibodies
Timepoint
every 6 months for 2 years, since 6 months after intervention,
Method of measurement
CPE method

4

Description
Adverse events
Timepoint
monthly afterwards for 2 years, scince one week after intervention weekly for the first month
Method of measurement
checklist

Intervention groups

1

Description
Avonex, 30, microgram, IM, weekly, for 104 weeks
Category
Treatment - Drugs

2

Description
Cinnovex, 30 microgram, IM, weekly, for 104 weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shariati Hospital
Full name of responsible person
Street address
City

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Cinnagen Company
Full name of responsible person
Haleh Hamedifar
Street address
5th floor, #56, Azimi Alley, Ekbatan-Phase 1
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Cinnagen 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
Cinnagen
Full name of responsible person
Shiva Salami
Position
Physician
Other areas of specialty/work
Street address
5th floor, #56, Azimi Alley, Ekbatan-Phase 1
City
Tehran
Postal code
Phone
+98 21 4466 6204
Fax
Email
shiva.salami45@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Shahriar Nafissi
Position
Neurologist
Other areas of specialty/work
Street address
Shariati Hospital
City
Tehran
Postal code
14114
Phone
+98 21 8490 2224
Fax
+98 21 2288 4420
Email
s_nafissi@yahoo.com, nafisi@sina.tums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Full name of responsible person
Shahriar Nafissi
Position
Other areas of specialty/work

Street address
City
Postal code
Phone
Fax
Email
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