

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 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 \leq 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® 30 μ g IM QW for 104 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-chancellor 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, since 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