# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

05 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*