

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jun 2026

### The Comparison of safety and Efficacy of ReciGen and Rebif in patients with Relapsing Multiple Sclerosis

#### Protocol summary

##### Summary

The objective of this study was to assess the efficacy and safety of ReciGen (Interferon beta-1-a, Subcutaneous, 3 times per week) in patients with multiple sclerosis, over a 24 months period. This study will be undertaken in 3 centers in Iran (Tehran, Esfahan and Qazvin). Patients with mild to moderate Relapsing-Remitting Multiple Sclerosis aged between 18-50 years and Expanded Disability Status Score (EDSS) between 0-5.5 will be randomized to receive Rebif (12 mIU/day, 3 days per week) or ReciGen (12 mIU/day, 3 days per week). The main efficacy measures will be the number of relapses, the change in EDSS score, MRI findings and neutralizing antibodies compared to baseline. In addition, side effects will be systematically recorded for both treatments.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201112201859N3**

Registration date: **2012-01-12, 1390/10/22**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2012-01-12, 1390/10/22

##### Registrant information

##### Name

Mohammad Ali Sahraian

##### Name of organization / entity

Tehran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6634 8571

##### Email address

msahrai@sina.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

CinnaGen Pharmaceutical Company, Tehran University of Medical Sciences

##### Expected recruitment start date

2008-03-05, 1386/12/15

##### Expected recruitment end date

2009-09-06, 1388/06/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The Comparison of safety and Efficacy of ReciGen and Rebif in patients with Relapsing Multiple Sclerosis

##### Public title

The Comparison of ReciGen and Rebif in patients with Relapsing Multiple Sclerosis

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

-Inclusion Criteria: 1.Relapsing-Remitting MS patients based on McDonald's Criteria 2.ages between 18-50 3.EDSS= $\leq$ 5.5 4.Signing informed consent form -Inclusion Criteria: 1.Pregnancy during trial or intention to get pregnant in start of trial 2.Psychiatric disease or major depression 3.Past history of Suicide 4.Allergy/hypersensitivity reaction to medication 5.IVIG treatment within 6 months prior to trial 6.Plasma Exchange within 6 months prior to trial 7.Cytotoxic Medication use during study 8.Impaired Liver Function Tests (3times NI range) 9.Leukopenia (less than half the NI range) 10.failure to follow-up for more than 4 weeks

(with recording the reason)

**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: **54**

**Randomization (investigator's opinion)**

Randomized

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

Triple 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 Ethics Committee

**Street address**

Tehran University of Medical Sciences, Qods St, Keshavarz Blv.

**City**

Tehran

**Postal code****Approval date**

2007-12-30, 1386/10/09

**Ethics committee reference number**

130/8020

**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**

Relapse Rate

**Timepoint**

every month

**Method of measurement**

Physical examination done by neurologist

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

EDSS

**Timepoint**

Every month

**Method of measurement**

Physical Examination done by Neurologist

**2****Description**

number/size of plaques and their enhancement

**Timepoint**

Every 6 months

**Method of measurement**

MRI

**3****Description**

Neutralizing Antibodies

**Timepoint**

Every 6 months

**Method of measurement**

measurment in peripheral blood (NU/ml)

**Intervention groups****1****Description**

Rebif Ampule, 12MIU, 3 times a week (Saturday,Monday,Wednesday), for 24 months

**Category**

Treatment - Drugs

**2****Description**

Recigen Ampule, 12MIU, 3 times a week (Saturday,Monday,Wednesday), for 24 months

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center**

Name of recruitment center

Dr Shariati Hospital

**Full name of responsible person**

Dr AmirReza Azimi

**Street address**

Jalal al Ahmad cross, Northern Kargar St.

**City**

Tehran

**2**

**Recruitment center**

**Name of recruitment center**

Buali Hospital

**Full name of responsible person**

Dr AmirReza Azimi

**Street address**

**City**

Qazvin

**3**

**Recruitment center**

**Name of recruitment center**

Azzahra Hospital

**Full name of responsible person**

Dr Masood Etemadifar

**Street address**

**City**

Esfahan

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Cinnagen Pharmaceutical

**Full name of responsible person**

Dr Shiva Salami

**Street address**

N2, 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

**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 Pharmaceutical

**Full name of responsible person**

Dr Shiva Salami

**Position**

General Physician/Clinical Research Manager

**Other areas of specialty/work**

**Street address**

N2, 7th Alley, Simay-e-Iran St, Shahrak-e-Qods

**City**

Tehran

**Postal code**

1466998741

**Phone**

+98 21 8856 1556

**Fax**

**Email**

shiva.salami45@yahoo.com;salamis@cinnagen.com

**Web page address**

www.cinnagen.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr AmirReza Azimi

**Position**

Neurologist/Assistant Professor

**Other areas of specialty/work**

**Street address**

Sina Hospital, Hasan abad Sq. , Imam Khomeini St.

**City**

Tehran

**Postal code**

1136746911

**Phone**

+98 21 6634 8571

**Fax**

+98 21 6634 8570

**Email**

amirreza\_azimi@yahoo.com

**Web page address**

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr MohammadAli Sahraian

**Position**

Neurologist-MS Fellowship/Associate Professor

**Other areas of specialty/work**

**Street address**

Sina Hospital, Hasan abad Sq. , Imam Khomeini St.

**City**

Tehran

**Postal code**

1136746911

**Phone**

+98 21 6634 8571

**Fax**

+98 21 6634 8570

**Email**

msahrai@sina.tums.ac.ir, sahraian1350@yahoo.com

**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*