Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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Mohammad Ali Sahraian
Name of organization / entity
Tehran University of Medical Sciences
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Iran (Islamic Republic of)
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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=<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 Nl range) 9.Leukopenia (less than half the Nl 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

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Person responsible for scientific inquiries

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Tehran University of Medical Sciences

Full name of responsible person

Dr AmirReza Azimi

Position

Neurologist/Assistant Professor

Other areas of specialty/work

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Full name of responsible person

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Position

Neurologist-MS Fellowship/Associate Professor

Other areas of specialty/work

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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