Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Imatinib Treatment for Secondary Progressive Multiple Sclerosis: A Randomized Control Trial Study Assessing Clinical and Radiological Responses and adverse effects in comparison with Novanterone

Protocol summary

Summary

Objectives: Imatinib Treatment for Secondary Progressive Multiple Sclerosis: A Randomized Control Trial Study Assessing Clinical and Radiological Responses and adverse effects in comparison to Novantrone. Design: Multiple sclerosis is a chronic degenerative autoimmune disorder which leads to demyelinating inflammation of white matter of central nervous system. Because of our incomplete knowledge of its pathogenesis, despite of extensive researches in this field there is no definite cure for multiple sclerosis. Recent investigations show that protein kinase inhibitors such as Imatinib can reduce macrophage activation and astrocytosis via inhibition of Tyrosine Kinase CSF-1 Receptor and PDGFRs related signaling. These pathways play crucial role in the pathogenesis of autoimmune diseases including multiple sclerosis. There upon, it is suggested that these drugs may have beneficial therapeutic effect in these disorders. According to lesser adverse effects of these drugs in comparison to FDA-approved treatment for SPMS such as Novantrone, confirmation of this idea can be an important step in treatment of this disabling disease. Conduct and setting: This project is a one-centric double-blind randomized control clinical trial. Interventions: After verifying the consensus form, Case group will receive Imatinib (400 mg PO daily), and control group will receive Novantrone according to accepted guidelines. Participants including major eligibility criteria: Inclusion criteria: SPMS patients with relapse. Exclusion criteria: History of chronic hematologic, renal, liver or infectious diseases; Pregnancy; history of cancer especially breast tumor; Major outcome: Number of relapse and EDSS changes and number of new plaques in MRI during six months; reported adverse effects.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201210231584N3**
Registration date: **2012-11-14, 1391/08/24**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2012-11-14, 1391/08/24

Registrant information

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Mohammad Hossein Harirchian
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Sciences

Expected recruitment start date

2012-11-21, 1391/09/01

Expected recruitment end date

2014-11-22, 1393/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Imatinib Treatment for Secondary Progressive Multiple Sclerosis: A Randomized Control Trial Study Assessing Clinical and Radiological Responses and adverse effects in comparison with Novanterone

Public title

The evaluation of therapeutic effects and adverse effects of Imatinib in Secondary Progressive Multiple Sclerosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: SPMS patients with relapse; EDSS between 3 and 5; age between 18 and 40 Exclusion criteria: History of other autoimmune disorder or chronic hematologic, renal, liver or infectious diseases; Pregnancy; lactation; History of HIV and Hepatitis; History of cancer especially breast tumor; History of recent herpes zoster infection; History of cytotoxic drugs consumption during recent three months; History of high dose corticosteroid during recent two months.

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **28**

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

Ethics committee of Tehran University of Medical Sciences

Street address

Ethics committee of Tehran University of Medical Sciences, 5th floor, Ghods St, Tehran University of Medical Sciences, Tehran, Iran

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Tehran

Postal code

Approval date

2012-05-23, 1391/03/03

Ethics committee reference number

91-02-54-18123-66824

Health conditions studied

1

Description of health condition studied

Multiple Sclerosis

ICD-10 code

G35

ICD-10 code description

Multiple sclerosis (MS), also known as

Primary outcomes

1

Description

Clinical signs and symptoms

Timepoint

every one month

Method of measurement

Number of relapses during six months, EDSS changes

2

Description

adverse effect

Timepoint

every one month

Method of measurement

biochemical test, clinical examination

Secondary outcomes

1

Description

Number of new plaques in MRI

Timepoint

six months

Method of measurement

Brain MRI with and without Gad

Intervention groups

1

Description

Case group receives Imatinib 400 mg daily (PO)

Category

Treatment - Drugs

2

Description
Control group will receive Novanterone according to accepted guidelines
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Iranian Center of Neurological Researches
Full name of responsible person
Dr Mohammad Hossein Harirchian
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
91-02-54-18123
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Tehran University of Medical Sciences
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

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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