

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

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

#### 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

##### Name

Mohammad Hossein Harirchian

##### Name of organization / entity

Tehran University of Medical Science, Iranian Center of Neurological Research

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8873 3731

##### Email address

harirchm@sina.tums.ac.ir

##### 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

**City**

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

##### Street address

Iranian Center of Neurological Researches, Imam Khomeini Hospital, Blvd Keshavarz, Tehran, Iran

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor for research, Tehran University of Medical Sciences

##### Full name of responsible person

Dr Fotuhi

##### Street address

Vice chancellor for research, Tehran University of Medical Sciences, Ghods Street, Tehran, Iran

##### City

Tehran

#### 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

### Contact

#### Name of organization / entity

Tehran University of Medical Sciences

#### Full name of responsible person

Dr Mohammad Hossein Harirchian

#### Position

Professor of Neurology

#### Other areas of specialty/work

#### Street address

Iranian Center of Neurological Researches, Imam Khomeini Hospital, Blvd Keshavarz, Tehran, Iran

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## Person responsible for scientific inquiries

### Contact

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Professor of neurology

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## Person responsible for updating data

### Contact

#### Name of organization / entity

Tehran University of Medical Sciences

#### Full name of responsible person

Dr Bahaadin Siroos

#### Position

Resident of Neurology

#### Other areas of specialty/work

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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*