

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 May 2026

### The effect of combined therapy with erythropoetin and methylprednisolone in severe relapse of Multiple Sclerosis patients

#### Protocol summary

##### Summary

The aim of the current study is to evaluate the effect of combined therapy of erythropoetin and methylprednisolone in comparison with methylprednisolone and placebo in clinical recovery of acute phase in MS patients. The population of the study is RR-MS or SP-MS patients in relapse motor. The population of study involved 20 patients which were randomly classified into two groups of ten patients. The patients in group one were under erythropoetin and methylprednisolone in five consecutive days and the patients in group two were under methylprednisolone and normal saline solution as a placebo. The patients of both groups were followed for EDSS and Ambulatory index after 4, 8 and 12 weeks and after three months, the patients were evaluated in MRI for T2, black hole and contrast enhancing lesions. Method: the current study was interventional, double blind, randomized and control with placebo. Inclusion criteria: definite diagnosis of MS , age between 18 and 45 years, motor force 3/5 or less at presentation Exclusion criteria: pregnancy, breastfeeding, history of diabetes mellitus, hypertension, hyperlipidemia, heavy cigarette smoking, ischemic heart disease, myocardial infarction, cerebrovascular accident The outcome of the study was to evaluate the comparison of EDSS and AI and MRI in two groups of the study.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013081914407N1**  
Registration date: **2013-08-30, 1392/06/08**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2013-08-30, 1392/06/08

##### Registrant information

###### Name

Fatemeh Najmi Varzaneh

###### Name of organization / entity

Sina Hospital

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2203 4019

###### Email address

b-baradaran@student.tums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Multiple Sclerosis research center of Sina hospital

##### Expected recruitment start date

2013-06-22, 1392/04/01

##### Expected recruitment end date

2013-09-21, 1392/06/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of combined therapy with erythropoetin and methylprednisolone in severe relapse of Multiple Sclerosis patients

##### Public title

The effect of erythropoetin on Multiple Sclerosis

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: definite diagnosis of MS; age between

18 and 45 years old and motor force 3/5 or less at presentation. Exclusion criteria: pregnancy; breastfeeding; history of diabetes mellitus, hypertension, hyperlipidemia, heavy cigarette smoking, ischemic heart disease, myocardial infarction, cerebrovascular accident; family history of ischemic heart disease and /or cerebrovascular accident before 45 years; presence of thrombocytosis; presence of polycythemia(hematocrite above 50% in males and above 45% in females); presence of CRF(chronic renal failure); history of any vasculitis or collagen vascular disease; use of contraceptive medication; use of iron substitution; past history of thromboembolic events and any kind of malignancy(treated or untreated).

#### **Age**

From **18 years** old to **45 years** old

#### **Gender**

Both

#### **Phase**

N/A

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **20**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Double blinded

#### **Blinding description**

#### **Placebo**

Used

#### **Assignment**

Parallel

#### **Other design features**

### **Secondary Ids**

empty

### **Ethics committees**

#### **1**

##### **Ethics committee**

###### **Name of ethics committee**

Tehran University of Medical Science

###### **Street address**

Tehran, Enqelab Sq, Pour sina Ave.

###### **City**

Tehran

###### **Postal code**

##### **Approval date**

2013-06-17, 1392/03/27

##### **Ethics committee reference number**

92/d/130/470

### **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**

EDSS

##### **Timepoint**

Before intervention, one, two three months after intervention

##### **Method of measurement**

Examination

#### **2**

##### **Description**

Ambulatory Index

##### **Timepoint**

Before intervention, one, two three months after intervention

##### **Method of measurement**

Examination

#### **3**

##### **Description**

MRI

##### **Timepoint**

Before intervention and three months after intervention

##### **Method of measurement**

Visual

### **Secondary outcomes**

#### **1**

##### **Description**

Blood Pressure

##### **Timepoint**

Before intervention, five day and one and three months after intervention

##### **Method of measurement**

Sphygmomanometer

#### **2**

##### **Description**

RBC count

##### **Timepoint**

Before intervention, five day and three months after intervention

##### **Method of measurement**

Laboratory

## Intervention groups

### 1

#### Description

In Intervention group, 20000 units IV Erythropoetin and 1000 mg methylprednisolone IV has been prescribed for five consecutive days.

#### Category

Treatment - Drugs

### 2

#### Description

In control group, Normal saline solution (1000 mg, IV) and methylprednisolone 1000 mg IV has been prescribed for five consecutive days.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Sina Hospital

**Full name of responsible person**

**Street address**

**City**

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Tehran university of medical science research assistance

**Full name of responsible person**

Dr. Shahin Akhundzade

**Street address**

Tehran keshavarz boulevard.

**City**

Tehran

#### Grant name

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Tehran university of medical science research assistance

**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**

Sina Hospital

**Full name of responsible person**

Dr. Fateme Najmi Varzaneh

**Position**

Neurology Resident

**Other areas of specialty/work**

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30 tir, Tehran

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najmi.f87@gmail.com

**Web page address**

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Sina Hospital

**Full name of responsible person**

Dr. Mohammad Ali Sahraian

**Position**

Associated Professor

**Other areas of specialty/work**

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30 tir, Tehran

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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. Fatemeh Najmi Varzaneh

**Position**

Neurology resident

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Najmi.f87@gmail.com; najmi\_f83@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*