

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

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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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Sina Hospital

Full name of responsible person

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Associated Professor

Other areas of specialty/work

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Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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Position

Neurology resident

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