

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

Evaluation the effect of Mitoxantrone and Mitoxantrone plus Methylprednisolone on Progressive Multiple Sclerosis

Protocol summary

Summary

The aim of this study is to compare the effect of mitoxantrone and mitoxantrone plus methylprednisolone on Progressive MS. Our study (a randomized clinical trial) will be performed on 70 patients suffering from progressive MS in two parallel groups. The first group (35 patients) will receive 20 mg mitoxantrone plus 500 mg methylprednisolone monthly for 6 months. The second group (35 patients) will receive the same dose of mitoxantrone plus 100 CC of 5% dextrose water monthly for 6 months. Two indices will be measured before the study, end of drug administration and 6 months after drug prescription completion: Expanded Disability Status Scale (EDSS) and MRI's plaque numbers. The results of the physical examination and laboratorial tests of both groups will be compared before and after treatment completion and 6 months after the trial.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201107145943N3**

Registration date: **2011-07-22, 1390/04/31**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-07-22, 1390/04/31

Registrant information

Name

Abolghasem Rahimdel Meibidi

Name of organization / entity

Yazd University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 35 1822 4001

Email address

rahimdel30142@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Deputy of Research, Yazd University of Medical Sciences

Expected recruitment start date

2010-03-21, 1389/01/01

Expected recruitment end date

2010-12-22, 1389/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of Mitoxantrone and Mitoxantrone plus Methylprednisolone on Progressive Multiple Sclerosis

Public title

Evaluation the effect of adding methylprednisolone to mitoxantrone on progressive multiple sclerosis treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: presence of progressive MS, age between 20 to 50 Exclusion criteria: Age below 20 or above 50, Immune deficiency, cancer, Pregnancy or breast feeding, Renal or heart failure, Leukopenia during the injection (the reduction of neutrophils to less than 1500/ml), having received corticosteroids within 6 months before the trial

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 70

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

Yazd University of Medical Sciences

Street address

Shahid baahonar Square

City

Yazd

Postal code

Approval date

2010-02-22, 1388/12/03

Ethics committee reference number

127469/1/17/پ

Health conditions studied

1

Description of health condition studied

Multiple Sclerosis

ICD-10 code

G35

ICD-10 code description

Demyelinating diseases of the central nervous system

Primary outcomes

1

Description

MRI plaque numbers

Timepoint

6 months and 1 year after the intervention

Method of measurement

Based on MRI imaging

2

Description

Expanded Disability Status Scale (EDSS)

Timepoint

6 months and 1 year after the intervention

Method of measurement

Based on definit idex

Secondary outcomes

empty

Intervention groups

1

Description

Control group: mitoxantrone 20 mg as well as methylprednisolone 500 mg monthly for 6 consecutive months

Category

Treatment - Drugs

2

Description

Intervention group: mitoxantrone 20 mg monthly for 6 consecutive months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid sadoughi hospital

Full name of responsible person

Ali Mellat Ardekani

Street address

Shahid sadoughi hospital, Safaaieh

City

Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Fatemeh Ezoddini

Street address

Shahid bahonar Square

City

Yazd

Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?

Yes

Title of funding source

Yazd 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**

Yazd University of Medical Sciences

Full name of responsible person

Ali Mellat Ardekani

Position

Assistant Professor

Other areas of specialty/work**Street address**

Safaayeh

City

Yazd

Postal code**Phone**

+98 35 1822 4001

Fax**Email**

Ali_mellat@ssu.ac.ir

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Yazd University of Medical Sciences

Full name of responsible person

Abolghasem Rahimdel

Position

Assistant Professor

Other areas of specialty/work**Street address**

Shahid sadoughi hospital, Safaayeh

City

Yazd

Postal code**Phone**

+98 35 1822 4001

Fax**Email**

rahimdel30142@ssu.ac.ir

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Yazd University of Medical Sciences

Full name of responsible person

Ali Mellat Ardekani

Position

Assistant Professor

Other areas of specialty/work**Street address**

Shahid sadoughi hospital, Safaayeh

City

Yazd

Postal code**Phone****Fax****Email**

ali_mellat@ssu.ac.ir

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