Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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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
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Person responsible for scientific inquiries

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Person responsible for updating data

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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