Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of methylprednisolon plus mitoxantrone in the treatment of progressive multiple sclerosis

Protocol summary

Summary

This is a clinical trial study aimed at the investigation of the effect of methylprednisolon plus mitoxantrone in the treatment of progressive multiple sclerosis in Yazd province. The patients will be assigned to receive 20mg mitoxantrone and 500mg methyl prednisolone or 20mg mitoxantrone and 100cc dextrose water 5% (6 monthly injections). Cranial nerves examination, muscular power at proximal and distal portion according to scale from 0 to 5, cerebellum examination, and the number of plaques will be done before and after the study and compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201012245393N1**
Registration date: **2011-04-05, 1390/01/16**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-04-05, 1390/01/16

Registrant information

Name
Hamid Reza Soltani.G
Name of organization / entity
Yazd Islamic Azad University, Medical Society of Medicine
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Shahid Sadooghi University of Medical Sciences and Health Services

Expected recruitment start date

2010-06-01, 1389/03/11

Expected recruitment end date

2010-12-01, 1389/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of methylprednisolon plus mitoxantrone in the treatment of progressive multiple sclerosis

Public title

The effect of methylprednisolon plus mitoxantrone in the treatment of progressive multiple sclerosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with progressive multiple sclerosis, Informed consent, age between 20-50 year
Exclusion criteria: HIV+ patients, cancer, heart failure, immunodeficiency patients, patients with neutrophil count less than 1500

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: **36**

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
Ethic Committee of Shahid Sadooghi Medical University

Street address
Central Organization of Shahid Sadooghi Medical University, Bahonar Sq, Yazd

City
Yazd

Postal code
8916978477

Approval date
2011-02-21, 1389/12/02

Ethics committee reference number
پ 127469/1/17

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
Expanded Disability Status Scale

Timepoint
6 months after the beginning of study

Method of measurement
by a checlkist, standard criteria

2

Description
muscular power after treatment

Timepoint
6 months after the beginning of study

Method of measurement
physical examination

3

Description
cerebellum symptoms

Timepoint
6 months after the beginning of study

Method of measurement
physical examination

4

Description
MRI findings (number of lesions) after treatment

Timepoint
6 months after the beginning of study

Method of measurement
MRI

5

Description
cranial nerves involvement

Timepoint
6 months after the beginning of study

Method of measurement
physical examination

Secondary outcomes

1

Description
heartburn

Timepoint
6 months after the beginning of study

Method of measurement
ask from patients

2

Description
vomitting

Timepoint
6 months after the beginning of study

Method of measurement
ask from patients

3

Description
anorexia

Timepoint
6 months after the beginning of study

Method of measurement
ask from patients

4

Description
hair loss
Timepoint
6 months after the beginning of study
Method of measurement
ask from patients

5

Description
leukopenia
Timepoint
6 months after the beginning of study
Method of measurement
through hematologic test CBC

Intervention groups

1

Description
Intervention group: 20mg Mitoxantrone plus 500 mg methylprodnisolon during 6 months follow up
Category
Treatment - Drugs

2

Description
Control group: 20mg mitoxantrone (injection) and 100cc dextrose water 5% (control) with six months follow up
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Sadooghi University of Medical Sciences and Health Services
Full name of responsible person
Dr Aabolghasem Rahimdel
Street address
City
Yazd

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Sadooghi University of Medical Sciences and Health Services
Full name of responsible person
Dr fatemeh ezaddini
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Research deputy, Central Organization, Bahonar sq, yazd
City
Yazd
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Sadooghi University of Medical Sciences and Health Services
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
Scientific Soceity of Medicine, Islamic Azad Univerisity branch Yazd
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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