

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 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

Country

Iran (Islamic Republic of)

Phone

+98 35 1623 1817

Email address

hrsgmed@yahoo.com

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

127469/1/17 پ

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 checklist, 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 methylprednisolon 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

Street address

Research deputy, Central Organization, Bahonar sq,

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City

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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

Full name of responsible person

Hamid Reza Soltani

Position

Student of medicine

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Person responsible for scientific inquiries

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branch Yazd**Full name of responsible person**

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Position

Student of Medicine

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

Yazd

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*