Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Efficacy and safety evaluation of oral tapering prednisolone following inravenous methyl prednisolone to improve outcome of multiple sclerosis relapses: A randomized, double-blind, placebo-controlled trial

Protocol summary

Study aim

Determine the efficacy and safety of two regimens in the treatment of acute multiple sclerosis with or without reducing the dose of corticosteroid received to improve the incapacity of MS patients

Design

Randomized double blind clinical trial with placebo control, 70 patients with multiple sclerosis, 1: 1 in each group

Settings and conduct

Bu-Ali Sina Hospital Sari, Patients are randomly assigned into test groups. Until the end of the trial, no patient or investigator are aware of which drug each patient receives. Only one person who is not involved in the sampling and registration of information is aware of the drug code (main drug and Placebo)

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age over 18 years old; Disability Status Scale (EDSS) 0 to 5.0 before the attack; Exclusion criteria: Corticosteroid susceptibility; Any worsening in symptoms that require a change in treatment; Patient with optic neuritis; No complete period of treatment by the patient; Patients with active and bleeding stomach ulcer; Patient with diabetes with uncontrolled blood sugar.

Intervention groups

Intervention group: methylprednisolone pulse period (3 to 5 days) + tapering dose of prednisolone 50 mg orally Manufacturing Co. Abureyhan 20 days Placebo group: methylprednisolone pulse period (3 to 5 days) + tapering dose of prednisolone 50 mg orally Construction Group pharmaceutics School of Pharmacy within 20 days

Main outcome variables

FSS (Functional Systems Scores); ARMS(Assessing Relapse in multiple Sclerosis); Disability Status Scale (EDSS); Patient's weight.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120314009297N6**
Registration date: **2019-10-13, 1398/07/21**
Registration timing: **registered_while_recruiting**

Last update: **2019-10-13, 1398/07/21**
Update count: **0**

Registration date

2019-10-13, 1398/07/21

Registrant information

Name

narjes hendouei

Name of organization / entity

mazandaran university of medical science

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-30, 1398/04/09

Expected recruitment end date

2020-06-29, 1399/04/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Efficacy and safety evaluation of oral tapering prednisolone following inravenous methyl prednisolone to improve outcome of multiple sclerosis relapses: A randomized, double-blind, placebo-controlled trial

Public title
The effect of tapering of prednisolone after pulse therapy in a MS attack

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age over 18 years Disability Status Scale (EDSS) 0 to 5.0 before the attack

Exclusion criteria:
Corticosteroid susceptibility Any worsening in symptoms that require a change in treatment Patient with optic neuritis Not complete Period of treatment by the patient A patient with active and bleeding stomach ulcer A patient with diabetes with uncontrolled blood sugar

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
Based on the method of the permutation blocks of size 4, individuals are randomly divided into two groups. Samples will be divided into two experimental and control groups based on permutation blocks (blocks of size 4). It will be listed according to six possible ways (AABB, ABAB, ...) randomly and the arrangement of receiving intervention will be determined accordingly.

Blinding (investigator's opinion)
Double blinded

Blinding description
Prednisolone and placebo tablets are completely similar in terms of color, size, smell and taste, produced by a completely similar manufacturing and packagings. Until the end of the study, no patient or researcher are aware of which drug each patient receives. Only one person who is not involved in sampling and data gathering is aware of the drug codes (medication or placebo)

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Mazandaran University of Medical Sciences

Street address
Moallem Street, Moallem Square, Vice Chancellor For Research

City
Sari

Province
Mazandaran

Postal code
33971-48157

Approval date
2019-06-17, 1398/03/27

Ethics committee reference number
IR.MAZUMS.REC.1398.570

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 (Expanded Disability Status Scale)and FSS(Functional Systems Scores) assessments that sustained increase in EDSS is considered as a change in measure from the start of the study. These two measures ultimately assess the incapacity of the MS and the course of the disease after receiving treatment.

Timepoint
The first month and the third month

Method of measurement
FSS, EDSS scale

Secondary outcomes

1

Description
Pulse methylprednisolone followed by oral prednisone Safety Assessment

Timepoint
The end of the first month

Method of measurement
Check list ARMS (assessment of relapse in multiple Sclerosis)

Intervention groups

1

Description
Intervention group: 1000 mg iv methylprednisolone for 5 days, followed by 50 mg oral prednisolone for 5 days, then 3/4 of prednisolone 50 mg for 5 days, then 1/2 prednisolone 50 mg for 5 days, then 1/4 mg prednisolone 50 mg for 5 days
Category
Treatment - Drugs

2

Description
Control group: 1000mg of methylprednisolone for 5 days, followed by 50 mg of oral placebo for 5 days, then 3/4 mg of the drug for 5 days, then 1/2 of the placebo for 5 days, then 1/4 mg of the drug for 5 Day (a total of 20 days, the placebo dose is reduced and discontinued)
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Bu-Ali Sina Hospital
Full name of responsible person
Narjes Hendouei
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
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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
Sari University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
I have not decided yet - its release plan is still unclear
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable