

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Efficacy and safety evaluation of oral tapering prednisolone following intravenous 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 pharmaceuticals 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)

Phone

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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 intravenous 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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pasdaran Blvd.Bu-Ali Sina Medical Education Center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Ahmad Ali Enayati

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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

Narjes Hendouei

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

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Latest degree

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Other areas of specialty/work

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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

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

Mazandaran University of Medical Sciences

Full name of responsible person

Narjes Hendouei

Position

Assistant professor

Latest degree

Specialist