Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

Effect of discontinuing immune-modulating drugs versus control group on prognosis in patients with relapsing-remitting multiple sclerosis: a single-blind randomized clinical trial

Protocol summary

Study aim

To assess the effect of discontinuing immune-modulating drugs versus control group on prognosis in patients with relapsing—remitting multiple sclerosis

Design

This is a Phase III single-blind randomized clinical trial with a control group with parallel groups, in which eligible patients will be randomly assigned to the intervention and control groups using block randomization.

Settings and conduct

This study will be conducted at the Besat Hospital in Hamadan city, involving 178 eligible patients with relapsing-remitting multiple sclerosis. The patients will be randomly assigned to the intervention and control groups through the block randomization. This trial will be single -blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 55 to 80 years Relapsing-remitting multiple sclerosis Taking drugs that modulate the immune system Exclusion criteria: Disease attack in the last 5 years Taking Tysabri or Fingolimod drugs

Intervention groups

Intervention group: Routine treatment of multiple sclerosis with the same dose that the patient has already received, plus stopping any immunosuppressive drugs (including dimethyl fumarate, triflunomide, interferons, glatiramer acetate, rituximab, ocrelizumab) and replacing them with an oral placebo for 24 months. Control group: Routine treatment of multiple sclerosis as well as the continuation of the use of immune system modulating drugs with the same dose as the patient has received before.

Main outcome variables

Primary outcome: Average disease severity, mean number of gadolinium-enhancing lesions

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N516**
Registration date: **2024-06-17, 1403/03/28**
Registration timing: **prospective**

Last update: **2024-06-17, 1403/03/28**
Update count: **0**

Registration date

2024-06-17, 1403/03/28

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-07-05, 1403/04/15

Expected recruitment end date

2025-01-04, 1403/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Effect of discontinuing immune-modulating drugs versus control group on prognosis in patients with relapsing-remitting multiple sclerosis: a single-blind randomized clinical trial

Public title
Effect of discontinuing immune-modulating drugs versus control group on prognosis in patients with relapsing-remitting multiple sclerosis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age 55 to 80 years Relapsing-remitting multiple sclerosis Taking drugs that modulate the immune system

Exclusion criteria:
Disease attack in the last 5 years Taking Tysabri or Fingolimod drugs

Age
From **55 years** old to **80 years** old

Gender
Both

Phase
3

Groups that have been masked

- Data analyser

Sample size
Target sample size: **178**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, random assignment of patients to the intervention and control groups will be carried out using block randomization. To achieve this, four sheets of paper will be prepared - two with the name of the intervention and two with the name of the control. These paper sheets will be pooled and placed in a container. Patients will be selected one at a time without replacement, and for each patient, a paper sheet will be randomly drawn from the container. After each draw, the paper sheets will be returned to the container, and the process will be repeated until the desired sample size is reached.

Blinding (investigator's opinion)
Single blinded

Blinding description
The analyzer responsible for evaluating the trial's results will also be kept blind to the type of interventions. Therefore, the trial will be conducted as a single-blind study.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Hamadan University of Medical Sciences

Street address
Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Fahmideh Ave

City
hamadan

Province
Hamadan

Postal code
6517838695

Approval date
2024-06-08, 1403/03/19

Ethics committee reference number
IR.UMSHA.REC.1403.166

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
Average disease severity

Timepoint
Before the intervention and 24 months later

Method of measurement
Based on the Extended Disability Status Scale (EDSS)

2

Description
Mean number of gadolinium-enhancing lesions

Timepoint
Before intervention and 24 months after

Method of measurement
Using MRI imaging

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Routine treatment of multiple sclerosis with the same dose that the patient has already received, plus stopping any immunosuppressive drugs (including dimethyl fumarate, triflunomide, interferons, glatiramer acetate, rituximab, ocrelizumab) and replacing them with an oral placebo for 24 months.
Category
Placebo

2

Description
Control group: Routine treatment of multiple sclerosis as well as the continuation of the use of immune system modulating drugs with the same dose as the patient has received before.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Besat Hospital in Hamadan city
Full name of responsible person
Dr Sajad Daneshyar
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Sponsors / Funding sources

1

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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
Hamedan 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
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available