Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

Evaluation of efficacy and safety of ozanimod in patients with multiple sclerosis: a clinical trial

Protocol summary

Study aim
The efficacy and safety of ozanimod in patients with relapsing-remitting multiple sclerosis.

Design
Single-arm, open-label, before-and-after interventional clinical trial.

Settings and conduct
This is a single-arm, open-label, before-and-after interventional clinical trial conducted at Ayatollah Kashani Educational and Medical Center in Isfahan, Iran. The study aims to evaluate the efficacy and safety of ozanimod in patients with relapsing-remitting multiple sclerosis (RRMS). Eligible participants will receive ozanimod hydrochloride at a daily dose of 0.5 milligrams for 24 months. Clinical outcomes will be assessed using the Expanded Disability Status Scale (EDSS), the Nine-Hole Peg Test (9HPT), and the Timed 25-Foot Walk Test (T25FW). Disease relapses, magnetic resonance imaging (MRI) lesions, and adverse events will also be recorded. The study will be conducted without blinding.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Written informed consent Age between 18 and 50 years Definite diagnosis of relapsing-remitting multiple sclerosis (RRMS) according to the 2024 McDonald criteria Expanded Disability Status Scale (EDSS) score less than 3.5 Exclusion Criteria: Pregnancy or breastfeeding Progressive forms of multiple sclerosis Cardiac conduction block Untreated severe obstructive sleep apnea Liver diseases Uncontrolled hypertension

Intervention groups
Eligible patients with relapsing-remitting multiple sclerosis (RRMS) receiving oral ozanimod hydrochloride 0.5 mg (equivalent to 0.46 mg ozanimod) once daily for 24 months.

Main outcome variables
Change in Expanded Disability Status Scale (EDSS) score following ozanimod treatment in patients with relapsing-remitting multiple sclerosis.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20171220037977N2**
Registration date: **2026-06-27, 1405/04/06**
Registration timing: **registered_while_recruiting**

Last update: **2026-06-27, 1405/04/06**
Update count: **0**

Registration date
2026-06-27, 1405/04/06

Registrant information
Name
Vahid Shaygannejad
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 31 3667 6292
Email address
shaygannejad@med.mui.ac.ir

Recruitment status
recruiting
Funding source

Expected recruitment start date
2025-07-24, 1404/05/02
Expected recruitment end date
2027-08-21, 1406/05/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

Evaluation of efficacy and safety of ozanimod in patients with multiple sclerosis: a clinical trial

Public title
Evaluation of efficacy and safety of ozanimod
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
written informed consent Age between 18 and 50 years Definite diagnosis of multiple sclerosis according to the 2024 McDonald criteria Relapsing-remitting multiple sclerosis (RRMS) EDSS score < 3.5 At least one documented relapse during the previous 24 months Patients previously treated with the first-line disease-modifying therapies or patients who experienced severe adverse affects from second-line therapies such as infection or treatment-resistant hypogammaglobulinemia
Exclusion criteria:
Pregnancy or breastfeeding Progressive forms of multiple sclerosis Cardiac conduction block Untreated severe obstructive sleep apnea Liver disease Uncontrolled hypertension
Age
From **18 years** old to **50 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Isfahan University of Medical Sciences, Hezarjerib Street, Isfahan, Iran
City
Isfahan
Province
Isfehan
Postal code
81746-73461
Approval date
2025-07-21, 1404/04/30
Ethics committee reference number
IR.MUI.MED.REC.1404.161

Health conditions studied

1

Description of health condition studied
Relapsing-remitting Multiple Sclerosis
ICD-10 code
G35
ICD-10 code description
Multiple sclerosis

Primary outcomes

1

Description
Change in Expanded Disability Status (EDSS) score in patients with relapsing-remitting multiple sclerosis following ozanimod treatment.
Timepoint
24 months after treatment initiation
Method of measurement
Disability status assessed using the standardized Expanded Disability Status Scale (EDSS) by a trained neurologist.

Secondary outcomes

1

Description
change in number of disease relapse in patients with relapsing-remitting multiple sclerosis during 24 months of Ozanimod treatment.
Timepoint
24 months after treatment
Method of measurement
The number of disease relapse recorded and assessed based on neurologist evaluation and review of patients' medical records.

Intervention groups

1

Description
Intervention group: Eligible patients with relapsing-remitting multiple sclerosis (RRMS) receiving ozanimod treatment. Participants will receive oral ozanimod hydrochloride 0.5 mg manufactured by Zist Darou (equivalent to 0.46 mg ozanimod) once daily for 24 months.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Kashani Hospital
Full name of responsible person
Vahid Shaygannejad
Street address
Ayatollah Kashani Hospital, Ayatollah Kashani Street, Isfahan, Iran
City
Isfahan
Province
Isfehan
Postal code
81746-73461
Phone
Fax
+98 913 313 3550
Email
Shaygannejad@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Vahid Shaygannejad
Street address
Isfahan University of Medical Sciences, Hezarjerib Street, Isfahan, Iran
City
Isfahan
Province
Isfehan
Postal code
81746-73461
Phone
+98 913 313 3550
Email
Shaygannejad@med.mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Vahid Shaygannejad
Position
professor
Latest degree
Medical doctor
Other areas of specialty/work
Neurology
Street address
Isfahan University of Medical Sciences
City
Isfahan
Province
Isfehan
Postal code
81746-73461
Phone
+98 31 3667 6292
Email
Shaygannejad@med.mui.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Vahid Shaygannejad
Position
Professor
Latest degree
Medical doctor
Other areas of specialty/work
Neurology
Street address
Isfahan University of Medical Sciences, Hezarjerib Street, Isfahan, Iran
City
Isfahan
Province
Isfehan
Postal code
81746-73461
Phone
+98 31 3667 6292
Email
Shaygannejad@med.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Vahid Shaygannejad

Position
Professor

Latest degree
Medical doctor

Other areas of specialty/work
Neurology

Street address
Isfahan University of Medical Sciences, Hezarjerib Street, Isfahan, Iran

City
Isfahan

Province
Isfehan

Postal code
81746-73461

Phone
+98 31 3667 6292

Email
Shaygannejad@med.mui.ac.ir

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