Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Nov 2026

Comparison of the effects of therapeutic doses of 500 and 1000 mg of Rituximab on the course of disability and radiographic changes in relapsing-remitting multiple sclerosis (RRMS) patients

Protocol summary

Study aim
Reducing treatment costs and drug side effects in RRMS patients

Design
This controlled, parallel-group, double-blind, randomized, phase 2 clinical trial will be conducted on 96 patients. A four-way block randomization method will be used for randomization.

Settings and conduct
The present study is a clinical trial that will be conducted at Besat Hospital in Hamadan over a period of one year on 96 patients with RRMS. By referring to the Neurology Department of Besat Hospital, we will first select 96 patients with RRMS who have a history of responding to treatment with rituximab. After obtaining informed consent, we will randomly divide them into two groups of 48. The first group will receive a reduced dose (500 mg or one vial) of rituximab once every 6 months, and the second group, as a control group, will receive a full dose (1000 mg or 2 vials) of rituximab once every 6 months. We will evaluate the response to treatment of these two groups by examining changes in the CD19+ Bcell population and Magnetic resonance imaging (MRI) radiographic changes, as well as the improvement in disability symptoms over the next 6 and 12 months.

Participants/Inclusion and exclusion criteria
1. Confirm diagnosis of RRMS 2. History of Rituximab use 3. History of adequate response to Rituximab

Intervention groups
Use of 500 or 1000 mg of Rituximab every 6 months in the comparison groups

Main outcome variables
changes in the CD19+ Bcell population and MRI radiographic changes, as well as the improvement in disability symptoms

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250301064890N1**
Registration date: **2025-03-12, 1403/12/22**
Registration timing: **prospective**

Last update: **2025-03-12, 1403/12/22**
Update count: **0**

Registration date
2025-03-12, 1403/12/22

Registrant information

Name
kimiya Etemady

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 38 3423 1538

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kimiyaetemady77@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-03-21, 1404/01/01

Expected recruitment end date
2026-03-20, 1404/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effects of therapeutic doses of 500 and 1000 mg of Rituximab on the course of disability and radiographic changes in relapsing-remitting multiple sclerosis (RRMS) patients

Public title
The effect of therapeutic doses of 500 mg of rituximab on the disability process in RRMS patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Confirm diagnosis of RRMS History of rituximab use History of adequate response to rituximab

Exclusion criteria:
Rejecting the diagnosis of RRMS The patient's need to change the type of medication taken during the study Urgent need to increase the dose of the drug during the study A sharp increase in the risk of recurrence of symptoms during the period of reducing the dose of the drug used.

Age
From **15 years** old to **90 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **96**

Randomization (investigator's opinion)
Randomized

Randomization description
Initially, the balanced block randomization method will be used, and then the four-block randomization method will be used. For this purpose, we will prepare four sheets of paper. On two sheets, we will write the letter I, meaning “Intervention,” and on the other two sheets, the letter C, meaning “Control.” The sheets will be mixed together and placed in a desk drawer. When each eligible patient visits, one of the sheets will be drawn at random and, based on whether the drawn sheet is I or C, they will be assigned to one of the two intervention groups. It should be noted that the drawn sheets will not be returned to the drawer until all four sheets have been drawn. After all four sheets have been drawn at random, all the sheets will be returned to the drawer and the above process will be continued for the next four patients until the desired sample size is reached.

Blinding (investigator's opinion)
Double blinded

Blinding description
In the face-to-face visit, patients will be examined by a physician who is unaware of the type of therapeutic intervention, so that judgment can be made in a blinded manner. The patient is also unaware of the treatment regimen received, and therefore the study design will be double-blind.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee in Biomedical Research, Hamadan University of Medical Sciences

Street address
Hamedan facing the people park

City
Hamadan

Province
Hamadan

Postal code
5617865178

Approval date
2024-10-08, 1403/07/17

Ethics committee reference number
IR.UMSHA.REC.1403.451

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
The human CD19 antigen is a 95 kd transmembrane glycoprotein belonging to the immunoglobulin superfamily. CD19 is classified as a type I transmembrane protein, with a single transmembrane domain, a cytoplasmic C-terminus, and extracellular N-terminus. CD19 is a biomarker for normal and neoplastic B cells, as well as follicular dendritic cells. CD19 is critically involved in establishing intrinsic B cell signaling thresholds through modulating both B cell receptor-dependent and independent signaling.

Timepoint
6 months and 1 year after the start of the therapeutic intervention

Method of measurement
CD19+ Bcell population

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Taking a reduced dose (500 mg or one vial) of rituximab once every 6 months
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Besat Hospital, Hamadan
Full name of responsible person
Neurology Department, Besat Hospital, Hamadan
Street address
Hamedan, Fatemi Blvd.
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6514845411
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Alireza Soltanian
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5617865178
Phone
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m_research@umsha.ac.ir
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
Name of organization / entity
Hamedan University of Medical Sciences
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Kimia Etemadi
Position
Medical student
Latest degree
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Person responsible for updating data

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Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

Neurology

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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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Only part of the data, such as information related to the main outcome or the like, can be shared.

When the data will become available and for how long

Year 2027

To whom data/document is available

We currently have no plans in this regard.

Under which criteria data/document could be used

We currently have no plans in this regard.

From where data/document is obtainable

We currently have no plans in this regard.

What processes are involved for a request to access data/document

We currently have no plans in this regard.

Comments