

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Oct 2026

Effects of Rapamycin on the gene expression of FoxP3 and GARP in CD4+CD25+FoxP3 Treg cells and evaluation of Tregs number and function in Multiple Sclerosis

Protocol summary

Summary

1-Aim: Multiple sclerosis (MS) is an autoimmune disease characterize by demyelinating plaque in the central nervous system. The disease has no cure and no recognized definite cause yet. Impaired CD4+CD25+FoxP3+ Treg cells are the possible cause. The available therapies are mostly immunosuppressive disease modifying agents. Rapamycin is an immunosuppressive agent with and tolerable side effects. The aim of the present clinical trial is to evaluate the therapeutic effects of rapamycin on the patients with MS. 2-Design: simple sampling method is used for patients. Eight patients were selected. 3- In this study, 8 patients with MS will be treated with rapamycin (2 mg/day) for six months and before and after the therapy the following parameters will be studied. Number of CD4+CD25+FoxP3+ Treg, FoxP3 expression rate Th1,2 and 17 cytokine levels, Number and size of the plaques 4- Patients/Inclusion/exclusion Inclusion Relapsing-Remitting MS, MRI records that proved the existence of demyelination, 0-6 expanded disability status scale (EDSS), lack of response to β interferon or glatiramer acetate, stopping β interferon or glatiramer acetate one month before the experimentation . Exclusion criteria: Primary progressive MS, history of immunosuppressive therapy, side effects of the drug, steroid therapy in the last one month, any sign of infection and cancer, cardiovascular and hematological disorders, high serum cholesterol and using medication for it, history of hepatic cirrhosis or other liver diseases that require treatment, history of C and B hepatitis, active CMV infection, renal diseases which require treatment, active lung diseases, diabetes, hyperthyroidism, infection with HIV, tuberculosis, history of alcohol misuse during last 6 months, phobia from MRI (Claustrophobia) and pregnant and lactating women 5- Trial: Six months of administration of rapamycin 2 mg per day 6- Main

variables: Number of CD4+CD25+FoxP3+ Treg, FoxP3 expression rate, Number and size of the plaques

General information

Acronym

Effects of Rapamycin on MS

IRCT registration information

IRCT registration number: **IRCT2012092510936N1**

Registration date: **2015-01-08, 1393/10/18**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-01-08, 1393/10/18

Registrant information

Name

Bahram Bagherpour

Name of organization / entity

Isfahan University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

This study was financially supported by Vice-chancellor of Research and Technology, Isfahan University of Medical Sciences, Isfahan, Iran (a fifth of the budget), Mr Ali Feiz (Three-fifths of the budget) and the rest, a fifth, was provided by the first author.

Expected recruitment start date

2012-11-09, 1391/08/19
Expected recruitment end date
 2013-05-09, 1392/02/19
Actual recruitment start date
 empty
Actual recruitment end date
 empty
Trial completion date
 empty

Scientific title
 Effects of Rapamycin on the gene expression of FoxP3 and GARP in CD4+CD25+FoxP3 Treg cells and evaluation of Tregs number and function in Multiple Sclerosis

Public title
 Effects of Rapamycin on multiple Sclerosis treatment

Purpose
 Treatment

Inclusion/Exclusion criteria
 Inclusion criteria: Relapsing- Remitting MS; MRI records that proved the existence of demyelination; 0-6 expanded disability status scale (EDSS); lack of response to β interferon or glatiramer acetate; stopping β interferon or glatiramer acetate one month before the experimentation . Exclusion criteria: primary progressive MS; history of immunosuppressive therapy; side effects of the drug; steroid therapy in the last one month; any sign of infection and cancer; cardiovascular and hematological disorders; high serum cholesterol and using medication for it; history of hepatic cirrhosis or other liver diseases that require treatment; history of C and B hepatitis; active CMV infection; renal diseases which require treatment; active lung diseases, diabetes, hyperthyroidism, infection with HIV, tuberculosis; history of alcohol misuse during last 6 months; phobia from MRI (claustrophobia) and pregnant and lactating women.

Age
 From **24 years** old to **27 years** old

Gender
 Both

Phase
 1

Groups that have been masked
No information

Sample size
 Target sample size: **8**

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

Ethical committee, Isfahan University of Medical Sciences

Street address

Ethical committee, Isfahan University of Medical Sciences

City

Isfahan

Postal code

Approval date

2012-05-02, 1391/02/13

Ethics committee reference number

391223

Health conditions studied

1

Description of health condition studied

relapsing remitting multiple sclerosis

ICD-10 code

G35-G37

ICD-10 code description

Demyelinating diseases of the central nervous system

Primary outcomes

1

Description

Reduction in plaque area and number, variation in the expesion of FOXP3 gene

Timepoint

Before and 6 months after the therapy with rapamycin

Method of measurement

MRI, real-time PCR

Secondary outcomes

1

Description

Th1, 2 and 17 Cytokine variation

Timepoint

Before and 6 months after therapy with rapamycin

Method of measurement

ELISA

Intervention groups

1

Description

FDA approved drug (Rapamycin) administrated to the patients, 2 mg daily for 6 months

Category

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Kashani Educational Hospital

Full name of responsible person

Street address

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor of Research and Technology, Isfahan
University of Medical Sciences, Isfahan, Iran

Full name of responsible person

Dr. Mehdi Nematbakhsh

Street address

Vice-chancellor of Research and Technology, Isfahan
University of Medical Sciences, Isfahan, Iran

City

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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

Vice-chancellor of Research and Technology, Isfahan
University of Medical Sciences, Isfahan, Iran

Proportion provided by this source

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

2

Sponsor

Name of organization / entity

Charity

Full name of responsible person

Mr. Ali Feiz

Street address

Seyed Al Shohada Hospital, Khayam St.

City

Isfahan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?

Yes

Title of funding source

Charity

Proportion provided by this source

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

3

Sponsor

Name of organization / entity

The researcher

Full name of responsible person

Bahram Bagherpour

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Isfahan University of Medical Sciences, Isfahan, Iran

City

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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

The researcher

Proportion provided by this source

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Department of Genetics and Molecular Biology,
School of Medicine, Isfahan University of Medical Sciences

Full name of responsible person

Mansour Salehi

Position

Ph.D. Staff member

Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty