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

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Name of organization / entity

Isfahan University of Medical Sciences

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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 rapamyin

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

Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Kashani Educational Hospital
Full name of responsible person
Street address
City
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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
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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.
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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
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
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Yes
Title of funding source
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Public or private sector
empty
Domestic or foreign origin
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Country of origin
Type of organization providing the funding
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Person responsible for general inquiries

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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