

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Study of the effects of therapeutic plasmapheresis in comparison with corticosteroid therapy on the frequency and ratio of Th17 and Treg cells

Protocol summary

Summary

The purpose of this study is evaluating the hypothesis that one mechanism by which plasmapheresis exert its effect on CD4+T cell mediated autoimmune diseases such as MS (Multiple Sclerosis), may be through affecting on the frequency, ratio and function of Th17 and regulatory T cells. We intend to compare the frequency of Th17 and Treg cells in 30 sample patients with Relapsing- Remitting MS in relapse phase, before and after undergoing an intravenous corticosteroid pulse or a complete course of plasmapheresis. In addition to assessment of the frequency of these cells by flow cytometry, expression levels of their characteristic transcription factors (RORC2 and FOXP3 for Th17 and regulatory T cells, respectively), is evaluated by real-time PCR. Also the plasma of these samples are collected and stored in -80°C for further studies. With clarifying the positive effects of plasmapheresis on counterbalancing the ratio and function of these T cells, this treatment will have the potential for reducing the rate and severity of future relapses in MS patients, in addition to relieving the symptoms of a present attack. Also, if this hypothesis is proven, continuing efforts can be proposed for specified filtering of the blood and depleting the body of defined inflammatory factors that promote the induction and function of proinflammatory T cells (Th17) or contrast with induction and function of regulatory T cells (Treg), instead of replacing the whole plasma, to perform a more effective and safe treatment for MS and similar autoimmune disorders.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012072110349N1**

Registration date: **2012-08-19, 1391/05/29**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2012-08-19, 1391/05/29

Registrant information

Name

Azam Jamshidian

Name of organization / entity

Isfahan University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2012-09-15, 1391/06/25

Expected recruitment end date

2013-01-01, 1391/10/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the effects of therapeutic plasmapheresis in comparison with corticosteroid therapy on the frequency and ratio of Th17 and Treg cells

Public title

Study of the effects of therapeutic plasmapheresis in comparison with corticosteroid therapy on the immune system of MS patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1- Relapsing-Remitting Multiple Sclerosis (RR-MS) patients with severe relapses, 2- Indicated for corticosteroid therapy, Or indicated for Plasma Exchange therapy 3- Satisfaction of patients to participate in the study 4- Not reception of any Immunomodulatory treatment atleast in last 2 months 5- Having more than 15 and less than 50 years age
Exclusion criteria: 1-Those patients who dont complete the course of therapy with any reason 2- Those patients who have not any of the above mentioned including criteria 3- Patients who have other types of MS disease apart from RR-MS

Age

From **15 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **10**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Medical School, Isfahan University of Medical Sciences

Street address

Medical School, Isfahan University of Medical Sciences, Isfahan, Iran

City

Isfahan

Postal code

Approval date

2011-05-31, 1390/03/10

Ethics committee reference number

390224

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

Regulatory T lymphocytes frequency

Timepoint

Before the first and at the end of last session of treatment

Method of measurement

Flowcytometry

2

Description

Th17 lymphocytes frequency

Timepoint

before the first and at the end of last session of treatment

Method of measurement

Flowcytometry

Secondary outcomes

1

Description

EDSS

Timepoint

1-2 weeks after last session of Plasma Exchange

Method of measurement

EDSS table (performs by a Neurologist)

Intervention groups

1

Description

Intra venous Methyl-prednisolone pulse 1mg/day in 3-5 days

Category

Treatment - Drugs

2

Description

Plasma Exchange as Intervention Corticosteroid received patients as Controls

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashani Hospital, MS clinic

Full name of responsible person

Street address

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Azam Jamshidian

Street address

Immunology Dept, Medical School, Isfahan University of Medical Sciences

City

Isfahan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Isfahan University of Medical Sciences

Proportion provided by this source

100

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

Isfahan University of medical Sciences

Full name of responsible person

Azam Jamshidian

Position

Ph.d Candidate in immunology

Other areas of specialty/work

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Web page address

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