Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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^{0}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
Iran (Islamic Republic of)
Phone
+98 31 1792 2431
Email address
jamshidian@resident.mui.ac.ir

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-Remiting Multiple Sclerosis (RR-MS) patients with severe relapses, 2- Indicated for corticoestroid 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
Befor 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 Corticoestroid 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
Street address
Isfahan University of Medical Sciences, Medical School, Immunology Dept.
City
Isfahan
Postal code
Phone
+98 31 1972 2431
Fax
Email
Jamshidian@resident.mui.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Isfahan University of Medical Sciences
Full name of responsible person
Azam Jamshidian
Position
Ph.D Candidate
Other areas of specialty/work
Street address
Immunology Dept, Medical School, Isfahan University of medical sciences
City
Isfahan
Postal code
Phone
+98 31 1792 2431
Fax
Email
Jamshidian@resident.mui.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Isfahan University of Medical Sciences
Full name of responsible person
Azam Jamshidian
Position
PhD Candidate
Other areas of specialty/work
Street address
Immunology dept, Medical School, Isfahan University of Medical Sciences
City
Isfahan
Postal code
Phone
+98 31 1792 2431
Fax
Email
jamshidian@resident.mui.ac.irAzamjamshidian@gmail.com
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