Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of Ozone Therapy and Routine Medical Treatment Effect on Disease Severity and Serum Level Changes of IL-33 in Patients with Multiple Sclerosis (MS)

Protocol summary

Study aim
The Purpose of this Study is to compare the Effectiveness of Ozone Therapy with Routine Medical Treatment in Patients with Multiple Sclerosis

Design
Parallel, single-blind, randomized clinical trial

Settings and conduct
66 Patients with MS that were referred to the manager's clinic of Kashan University of Medical Sciences, Kashan, Iran will be selected in the study. Patients will be divided into two groups. Patients of the control group will recieve medical treatment. Patients of the intervention group will recieve medical treatment and undergo ozone therapy. The changes of disease severity and serum levels of IL-33 will be determined and compared in patients at the beginning and at the end of the intervention.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Age 20-60 years. Having Multiple Sclerosis(EDSS=0-4.5) Exclusion Criteria: Having any local or systemic inflammation

Intervention groups
Control group: Receiving routine medical treatment(IFN-β) Intervention group: Receiving routine medical treatment(IFN-β) + ozone therapy

Main outcome variables
Disease severity; serum level of interleukin 33

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20171105037262N3**
Registration date: **2018-03-14, 1396/12/23**
Registration timing: **registered_while_recruiting**

Last update: **2019-01-04, 1397/10/14**
Update count: **1**

Registration date
2018-03-14, 1396/12/23

Registrant information

Name
mohammadhossein pourhanifeh

Name of organization / entity
kashan university of medical science

Country
Iran (Islamic Republic of)

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+98 31 5558 0988

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-03-11, 1396/12/20

Expected recruitment end date
2018-06-10, 1397/03/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of Ozone Therapy and Routine Medical Treatment Effect on Disease Severity and Serum Level Changes of IL-33 in Patients with Multiple Sclerosis (MS)

Public title
Ozone Therapy Effect on Multiple sclerosis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having Multiple Sclerosis EDSS=0-4.5

Exclusion criteria:

Unwillingness to continue cooperation Any local or systemic inflammation

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

After specifying the sample size, the first four blocks of A and B letters are formed (6 blocks). Then, each of the blocks is numbered 1 to 6 and based on the selected numbers from random numbers table, we form a sequence of blocks, in which the letters A and B are located, and then randomly one of the letters are considered as the drug group and the other letter as the control group. This method is referred to as "Termuted Blocked Randomization".

Blinding (investigator's opinion)

Single blinded

Blinding description

Since this is a single-blind study, our blindness would be single-blinded.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kashan University of Medical Science

Street address

Ghotb-e-Ravandi Blvd

City

Kashan

Province

Isfehan

Postal code

8715988141

Approval date

2018-02-12, 1396/11/23

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1396.111

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

Disease severity

Timepoint

At the beginning of the intervention

Method of measurement

Questionnaire

2

Description

IL-33

Timepoint

At the beginning of the intervention

Method of measurement

ELISA

Secondary outcomes

1

Description

Disease severity

Timepoint

At the end of the intervention

Method of measurement

EDSS

2

Description

IL-33

Timepoint

At the end of the intervention

Method of measurement

ELISA

Intervention groups

1

Description

Control group: Patients of this group will use interferon

beta as a routine medical treatment for six months. EDSS will be assessed for each patient before and after treatment, and blood sample will be collected. Each blood sample will be sent to the laboratory to measure the serum levels of IL-33 by ELISA and with the MyBiosource product kit of the United States.

Category

Treatment - Drugs

2

Description

Intervention group: Patients in this group, in addition to interferon beta (routine medical treatment), based on the severity of disease, will undergo ozone therapy as major autohemotherapy with standard doses. EDSS will be assessed for each patient before and after treatment, and blood sample will be collected. Each blood sample will be sent to the laboratory to measure the serum levels of IL-33 by ELISA and with the MyBiosource product kit of the United States.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Beheshti hospital

Full name of responsible person
Ebrahim Kouchaki

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kashan University of Medical Sciences

Full name of responsible person
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research@kaums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kashan 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
Bagheiat-allah University of Medical Sciences

Full name of responsible person
Hassan Nikoueinejad

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Immunology

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact
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Position
Student
Latest degree
A Level or less
Other areas of specialty/work
General Practitioner
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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
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available