Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Evaluation of the effect of vitamin C on frequency and severity of flu-like syndrome in multiple sclerosis patients receiving beta-interferon

Protocol summary

Study aim

Evaluation of the effect of vitamin C on frequency and severity of flu like syndrome in Multiple Sclerosis patients receiving beta interferon

Design

Controlled trial with intervention and control groups, parallel groups, triple blind study, randomized based on the permuted block technique with block size equal to four on the basis of Random allocation ratio software, third phase, 100 patients

Settings and conduct

Among the patients referred to the treatment centers affiliated to the Department of Neurology of Shiraz and Tehran University of Medical Sciences who meet the inclusion criteria, 100 people were included in the study and divided into intervention and control groups. Patient, researcher and analyzer don't know whether the patient is in intervention or control group and then a person who is trained by the researcher will give vitamin C to one group and placebo to the other group every night for three months. At the end of the first, second and third months of the study, all patients will be evaluated for flu like symptoms after receiving beta interferon (fever, chills, muscular pain, weakness). In fact, the patient scores each of his symptoms from 0 to 3 and at the end these scores are compared in both the intervention and control groups.

Participants/Inclusion and exclusion criteria

1.Patients who have Multiple Sclerosis according to McDonald criteria. 2.Beta-interferon is prescribed for them for the fist time.

Intervention groups

A 250 mg vitamin C tablet is given to intervention group every night for three months. A placebo tablet is given to control group every night for three months.

Main outcome variables

Fever, Chills, Muscular pain, Weakness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211122053145N2**
Registration date: **2023-06-17, 1402/03/27**
Registration timing: **registered_while_recruiting**

Last update: **2023-06-17, 1402/03/27**
Update count: **0**

Registration date

2023-06-17, 1402/03/27

Registrant information

Name

Maryam Poursadeghfard

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3484 5794

Email address

poursadra@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-30, 1402/02/10

Expected recruitment end date

2023-08-01, 1402/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of vitamin C on frequency and severity of flu-like syndrome in multiple sclerosis patients receiving beta-interferon

Public title

Evaluation of the effect of vitamin C on flu-like syndrome in multiple sclerosis patients receiving beta-interferon

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who have Multiple Sclerosis according to McDonald criteria. Beta-interferon is prescribed for them for the first time.

Exclusion criteria:

Patients who don't want to participate in this project. Patients that take vitamin C themselves. Patients who receive drugs other than beta-interferon for treatment of Multiple Sclerosis. Patients who have other autoimmune diseases or underlying diseases except Multiple Sclerosis.

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are divided into A and B groups through the randomization method based on the permuted block technique considering block size equal to four on the basis of Random allocation ratio software.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Patient, researcher and analyzer don't know whether the patient is in intervention or control group and a person who is trained by the researcher will give vitamin C to one group and placebo to the other group.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Shiraz University of Medical Sciences, Zand street, Shiraz

City

Shiraz

Province

Fars

Postal code

7134814336

Approval date

2019-07-28, 1398/05/06

Ethics committee reference number

IR.SUMS.REC.1398.707

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

Severity of fever

Timepoint

The end of the first, second and third month

Method of measurement

Scoring from 0 to 3 by asking the patient (zero means no symptoms, one means mild symptoms, two moderate and three severe symptoms)

2

Description

Severity of chills

Timepoint

The end of the first, second and third month

Method of measurement

Scoring from 0 to 3 by asking the patient (zero means no symptoms, one means mild symptoms, two moderate and three severe symptoms)

3

Description

Severity of body pain

Timepoint

The end of the first, second and third month

Method of measurement

Scoring from 0 to 3 by asking the patient (zero means no

symptoms, one means mild symptoms, two moderate and three severe symptoms)

4

Description
Severity of weakness
Timepoint
The end of the first, second and third month
Method of measurement
Scoring from 0 to 3 by asking the patient (zero means no symptoms, one means mild symptoms, two moderate and three severe symptoms)

5

Description
Severity of flu like syndrome
Timepoint
The end of the first, second and third month
Method of measurement
Total scores of fever, chills, body pain, weakness

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Daily intake of one 250 mg vitamin C chewable tablet made by Osve company for three months
Category
Rehabilitation

2

Description
Control group: Daily intake of a placebo pill similar to vitamin C made by Shiraz University of Medical Sciences pharmaceutical company for three months
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Clinic
Full name of responsible person
Maryam Poursadeghfard
Street address
Imam Reza specialized and sub-specialized clinic, next to Namazi Hospital, Namazi Square, Shiraz
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7134814734
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2

Recruitment center
Name of recruitment center
Medical centers affiliated to the Neurology Department of Tehran University of Medical Sciences
Full name of responsible person
Maryam Poursadeghfard
Street address
Tehran University of Medical Sciences, Qods Corner, Keshavarz Blvd
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tumspr@tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Mohammad Hashem Hashempour
Street address
Shiraz University of Medical Sciences, Zand Street, in front of Palestine Street, Shiraz
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7134814336
Phone
+98 71 3230 5410
Email
info@sums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Maryam Poursadeghfard
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Neurology
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Person responsible for updating data

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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
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available