Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of vitamin C on flu-like syndrome in MS patient after starting beta-interferon

Protocol summary

Study aim
the effect of vitamin C on flu-like syndrome in MS patient after starting beta-interferon

Design
A randomized clinical trial, triple-blind, placebo-controlled

Settings and conduct
The present study will be conducted as a clinical trial on MS patients receiving interferon, after permission from the Ethics Committee of Shiraz University of Medical Sciences. Patients will be randomly divided into two groups. Treatment group: receiving vitamin C 250mg after admission for 3 months. 2. Placebo group: receiving vitamin C-like pills with starch content for 3 months. All patients will be evaluated at the end of each months for symptoms of flu-like syndrome such as fever, chills and muscle pains, and the severity of the syndrome. Flu-like syndrome symptoms score is used to evaluate patients to achieve FLS-S. Each patient scores for each symptom, and each symptom is evaluated separately. 0 = no sign, 1 = mild (no disruption in daily activities), 2 = moderate (partial disruption in daily activities), 3 = severe (need to rest at home). The scores of each symptom is calculated and summed with other symptoms, such that the FLS-S scores between 0 and 12, and the severity of the syndrome is classified according to the following scale: Mild: 0-4 Medium: 5-8, Severe: 9-12. At the end, the mean of three scores is calculated and measured in each month and then compared between the two groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria:MS Patients who are taking interferon for the first time. Exclusion criteria: MS patients who have undergone interferon therapy for some time. Patients who do not wish to participate in the project.

Intervention groups
MS patients receiving interferon that are divided into two groups receiving Vit C and placebo.

Main outcome variables
symptoms of flu-like syndrome such as fever, chills and muscle pains, as well as the severity of the syndrome.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190731044396N1**
Registration date: **2019-10-02, 1398/07/10**
Registration timing: **registered_while_recruiting**

Last update: **2019-10-02, 1398/07/10**
Update count: **0**

Registration date
2019-10-02, 1398/07/10

Registrant information

Name
Maryam poursadeghfard

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 71 3612 1065

Email address
poursadegh@sums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-08-23, 1398/06/01

Expected recruitment end date
2020-03-05, 1398/12/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
The effect of vitamin C on flu-like syndrome in MS patient after starting beta-interferon

Public title
The effect of vitamin C on flu-like syndrome in MS patient

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
MS patients based on the McDonald's 2017 Criterion, taking interferon for the first time.

Exclusion criteria:
A patient with MS who has been on the interferon therapy for some time Patients who do not wish to participate in the study.

Age
From **20 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
patients were divided into control and case groups using permutation block randomization method with block size equal to 4, randomization list was generated based on Random allocation ratio software.

Blinding (investigator's opinion)
Triple blinded

Blinding description
The study is a triple-blind study. Neither the researcher nor the analyzer are aware of the patient being placed in the case or control group. The other person who trained by researcher, gives placebo or Vit C, which are similar in appearance and taste to the main drug (interferon), and both of them are stored at room temperature. After selecting Vit C and placebo groups, each patient in case group will receive a 250mg Vit C chew-able tablet each night from the Osveh and Patients in control group will receive a placebo-coated tablet similar to the Vit C tablet that are studied by Shiraz Pharmacy School.

Placebo
Used

Assignment
Other

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
Zand Street, Shiraz University of Medical Sciences

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
FLS in MS Pt that receives beta interferon

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Fever and chills, weakness, muscle body pain

Timepoint
first, second and third months

Method of measurement
flu like syndrome symptoms score

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: administration of daily Vit C (250mg) for 3 months

Category
Rehabilitation

2

Description

Control group: administration of daily placebo tablets for 3 months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina clinic and Emam Reza clinic

Full name of responsible person

Maryam Poursadegh fard

Street address

Zand street, Emam Reza Clinic

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71473771348

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr.Younes.Ghasemy

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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

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

Associate professor

Latest degree

Specialist

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)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is 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

Title and more details about the data/document
Part of the data is the main consequence of the study

When the data will become available and for how long
Start the access period 6 months after printing the results

To whom data/document is available
Researchers working in academia and industry

Under which criteria data/document could be used
Supporting use

From where data/document is obtainable
Dr. Maryam Poursadegh fard poursadegh@sums.ac.ir

What processes are involved for a request to access data/document
After submitting the request and checking the available items,The data is obtained

Comments