Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Study of effect of Silybum marianum fruit extract on fatigue in patients with multiple sclerosis: double blind, clinical trial

Protocol summary

Study aim
The aim of this study was to evaluate effects of Silybum marianum fruit extract on fatigue of multiple sclerosis patients

Design
This study was a double-blind, controlled trial, 33 patients with MS were assigned in each group.For randomization, the permuted block randomization will be used with quadruple blocks, In order to apply the concealment in the randomization process, unique codes, which is generated by the software, will be used on the drug boxes

Settings and conduct
All patients referred to Imam Golestan Hospital of Ahvaz, Iran, were assigned randomly in one of the treatment regimens for 4 weeks

Participants/Inclusion and exclusion criteria
Inclusion criteria: MS patients have fatigue; No other neurological disease; No Diseases like diabetes and autoimmune diseases; No new attack in the last month
Exclusion criteria: Emergence of drug side effects; New disease attack; Do not take medicine for one week; Pregnancy

Intervention groups
Intervention group: Interferon (main treatment) with Milk thistle capsules (420 mg daily) for one month

Main outcome variables
MSQL-54 questionnaire; MFIS questionnaire

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20111105008013N8**
Registration date: **2020-01-26, 1398/11/06**
Registration timing: **registered_while_recruiting**
Last update: **2020-01-26, 1398/11/06**
Update count: **0**

Registration date
2020-01-26, 1398/11/06

Registrant information

Name
Amir Siahpoosh

Name of organization / entity
Ahvaz Jundishapur University of Medical Sciences

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-01-10, 1398/10/20

Expected recruitment end date
2020-02-09, 1398/11/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Study of effect of Silybum marianum fruit extract on fatigue in patients with multiple sclerosis: double blind, clinical trial

Public title
Investigating of Silybum marianum fruit extract on MS fatigue

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Multiple sclerosis patients have fatigue Ages between 15-65 years old

Exclusion criteria:

other neurological disease Diseases like diabetes and autoimmune diseases new attack in the last month New disease attack Pregnancy

Age

From **15 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

For randomization, the permuted block randomization will be used with quadruple blocks. blocks will be produced by using the online site (www.sealedenvelope.com)

Blinding (investigator's opinion)

Double blinded

Blinding description

Unique codes, which is generated by the software, will be used on the drug boxes. By entering each individual into the study based on the produced sequence, the drug box in which the code is registered, will be assigned to the individual. During the research, the randomization list is held by the statistic consultant, and the participants, the project implementer and all those who participate in the measurement of the indicators will not be aware of the assigned groups

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ahvaz Jundishapur University of Medical Sciences

Street address

Golestan Road

City

Ahvaz

Province

Khouzestan

Postal code

6135733184

Approval date

2018-12-22, 1397/10/01

Ethics committee reference number

IR.AJUMS.REC.1397.695

Health conditions studied

1

Description of health condition studied

Multiple sclerosis

ICD-10 code

G35

ICD-10 code description

Multiple sclerosis

2

Description of health condition studied

Neurasthenia

ICD-10 code

F48.0

ICD-10 code description

Neurasthenia

Primary outcomes

1

Description

Fatigue

Timepoint

Start intervention and a month later

Method of measurement

MFIS questionnaire

2

Description

Quality of Life

Timepoint

Start intervention and a month later

Method of measurement

MSQL-54 questionnaire

Secondary outcomes

1

Description

Side effects

Timepoint

One month after the intervention began

Method of measurement

Observation

Intervention groups

1

Description
Intervention group: Interferon (main treatment) with Milk thistle capsules (420 mg daily) for one month
Category
Treatment - Drugs

2

Description
Control group: Interferon (main treatment) with placebo capsules (three times a day) for one month
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Golestan Hospital in Ahvaz
Full name of responsible person
Amir Siahpoosh
Street address
Medicinal Plants Research Center and Deparment of Pharmacognosy, Faculty of Pharmacy, Ahvaz Jundishapur University of medical Sciences, Ahvaz, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Dr Mohamad badavi
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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
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Amir Siahpoosh
Position
Assaciate professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
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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
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Only a part of the data will be shared

When the data will become available and for how long
The access period will be 6 months after the publication of the results

To whom data/document is available
The information obtained will only be available to researchers working in universities and science centers

Under which criteria data/document could be used
Six months after the publication of this study papers, the obtained data will be available to the applicant researchers for further analysis

From where data/document is obtainable
Applicants can be contacted with corresponding author by e-mail

What processes are involved for a request to access data/document
Applicants will be able to access the obtained data from current study by sending an email to the corresponding author up to one month

Comments