Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of vitis vinifera seed extract on fatigue of MS patients

Protocol summary

Summary

This double-blind randomized controlled trial will be conducted to evaluate the effect of grape seed on fatigue in MS patients. This double-blind randomized controlled trial will be conducted to evaluate the effect of grape seed on fatigue in MS patients. From patients referred to Ahvaz Golestan Hospital from March 2017 to March 2018, 66 ones with M.S. fatigue between the ages of 15 and 65 are included in the present study. They will be divided into two treatment and control groups. Patients will be excluded from the study if they are pregnant, affected by drug side effects, etc. In addition to a primary drug (interferon), both groups will receive grape seed capsules (300 mg of extract) or placebo capsules twice a day for one month. The Modified Fatigue Impact Scale (MFIS) and Multiple Sclerosis Quality of Life-54 (MSQl-54) questionnaires will be used to evaluate patients. The questionnaires will be completed by a specialist at the beginning and 1 month after the treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201708218013N1**
Registration date: **2017-11-07, 1396/08/16**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-11-07, 1396/08/16

Registrant information

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Ahvaz Jundishapur University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2017-03-20, 1395/12/30

Expected recruitment end date

2018-03-21, 1397/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of vitis vinifera seed extract on fatigue of MS patients

Public title

Investigating of red grape seeds on MS fatigue

Purpose

Treatment

Inclusion/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

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

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

Ahvaz, golestan road

City

Ahvaz

Postal code

Approval date

2017-05-22, 1396/03/01

Ethics committee reference number

IR.ajums.REC.1396.326

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

MFIS

Timepoint

Start intervention and a month later

Method of measurement

MFIS questionnaire

2

Description

MSQL-54

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

Control group: Interferon (main treatment) with placebo capsules (twice daily) for one month

Category

Treatment - Drugs

2

Description

Treatment group: Interferon (main treatment) with grape seed capsules (twice daily) for one month, each capsule contained 300 mg extract

Category

Treatment - Drugs

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

City
Ahvaz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz Jundishapur University of Medical Sciences, medicinal plants research center
Full name of responsible person
Dr Behzad Sharif Makhmalzadeh
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ahvaz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz Jundishapur University of Medical Sciences, medicinal plants research center
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

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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