Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of evening primrose oil on fatigue and quality of life in patients with multiple sclerosis

Protocol summary

Summary

This study aims to investigate the effects of evening primrose oil on fatigue and quality of life in patients with multiple sclerosis design study: For example: a randomized, double-blind, controlled placebo study population: people 15 to 55 years old with MS, the main criteria entry to study: a diagnosis based on neurological examination and magnetic resonance imaging confirmed by a doctor neurologist is sent. B :) people 15-55 years c EDSS scores less than 6 (d) of patients in the last month attack (attack) is not new and they did not use the pulse corticosteroids. Main exclusion criteria: (a) the emergence of side effects of discontent from the study (c) of the drug for a week of pregnancy Sample Size: 60 (b) intervention or interventions studied: Medication evening primrose oil group (c) intervention and control intervention time: 3 months (d) the primary outcome: 1) reduce fatigue 2) improving quality of life

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015101324520N1**
Registration date: **2016-01-27, 1394/11/07**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-01-27, 1394/11/07

Registrant information

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Name of organization / entity

Medical Science Jundishapur

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Recruitment status

Recruitment complete

Funding source

vice chancellor for research،Jundishapur university of medical sciences

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2015-10-23, 1394/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of evening primrose oil on fatigue and quality of life in patients with multiple sclerosis

Public title

The effect of evening primrose oil in the treatment of multiple sclerosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1) The diagnosis of the neurological examination and magnetic resonance imaging confirmed by a doctor neurologist is sent. 2) persons 15-55 years 3) EDSS score of less than 6, 4) neurological diseases such as stroke or psychiatric, such as depression or not. 5) pregnant women are not tested. 6) autoimmune diseases like lupus or rheumatoid arthritis, and heart as Bdkhymy-not. 7) patients in the last month attack (attack) is not

new and they did not use the pulse corticosteroids.";" Exclusion criteria: 1) the emergence of drug complications 2) resentment of the presence in the study 3) of the drug for a week 4) Pregnancy

Age
From **15 years** old to **55 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Single

Other design features
Using sequences of four permutation

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee Of Jundishapur University Of Medical Science

Street address
Jundishapur University Of Medical Sciences Golestan Ahvaz

City
Ahvaz

Postal code

Approval date
2015-09-19, 1394/06/28

Ethics committee reference number
IR.Ajums.REC.1394.348

Health conditions studied

1

Description of health condition studied
Multiple sclerosis

ICD-10 code
G35-G37

ICD-10 code description
Demyelinating diseases of the central nervous system

Primary outcomes

1

Description
quality of life

Timepoint
Before and 3 months after intervention

Method of measurement
Quality of Life in this study using a questionnaire with 54 questions were Vickrey and colleagues. sclerosis

Secondary outcomes

1

Description
Fatigue

Timepoint
Before and 3 months after intervention

Method of measurement
MFIS was measured using the scale of fatigue in multiple sclerosis

Intervention groups

1

Description
Capsules of evening primrose oil 1 g orally 2 times a day for 3 months in the intervention group

Category
Treatment - Drugs

2

Description
1 gram oral placebo capsules 2 times a day for 3 months in the control group Manufacturer: Barij Essence

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Teaching Hospitals Of Golestan Ahvaz

Full name of responsible person
N. Majdinasab Associate Professor Of Neurology

Street address
Khuzestan, Ahvaz Golestan Hospital Department Of Neurology

City
Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor For Research Of Jundishapur University Of Medical Sciences

Full name of responsible person
Nader Saki

Street address
Golestan University Of Medical Sciences, Ahvaz City, Khuzestan, Ahvaz, the research center

City
Ahvaz

Grant name

Grant code / Reference number

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

Title of funding source
Vice Chancellor For Research Of Jundishapur University Of Medical Sciences

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

Contact

Name of organization / entity
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Associate Professor Of Neurology

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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