Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Clinical trial comparing the effects of fish liver oil and Boswellia Serrata with placebo on fatigue of multiple sclerosis patients

Protocol summary

Summary

Clinical trial comparing the effects of fish liver oil and boswellia serrata with placebo on fatigue of multiple sclerosis patient. In this study we used fish liver oil- with its large amounts of omega 3- and Boswellia Serrata concrete in MS patients and evaluated its effects on these patients' fatigue scale. Material: In this study, we selected 65 multiple sclerosis patients among those who referred to the multiple sclerosis consultation center. All of them were under treatment with interferon and no-one had major depression (according to depression beck scale). They were separated into three groups, one receiving placebo (21 patients: capsules filled with starch) in addition to interferon. Second group got liver fish oil in addition to interferon. Third group got boswellic acid. These drugs were packaged and encoded with pharmacognosis department of Ahvaz Jundishapour University of Medical Science and were given to patients with multiple sclerosis society of Khoozestan. So, it is double blinded study because patients and researchers did not know about type of drug used. After one month of follow up, fatigue scales were collected and then compared to the pre-test scales of fatigue, applying a paired t- test

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013020812399N1**
Registration date: **2013-09-30, 1392/07/08**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-09-30, 1392/07/08

Registrant information

Name
Salman Fatemi
Name of organization / entity
Ahvaz Jundishapour University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Ahvaz Jundishapour University of Medical Science

Expected recruitment start date

2010-11-22, 1389/09/01

Expected recruitment end date

2013-01-19, 1391/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial comparing the effects of fish liver oil and Boswellia Serrata with placebo on fatigue of multiple sclerosis patients

Public title

Comparing the effects of fish liver oil and Boswellia Serrata with placebo on multiple sclerosis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : 1- Age between 20 and 55 2- Multiple sclerosis patients taking Interferon 4- No new emotional stress when the patients are under the study 5- No

cytotoxic therapy Exclusion criteria : 1-Younger than 20 and older than 55 2-Intake of corticosteroid pulse during study 3- New emotional stress on the patient during study 4- New multiple sclerosis attack during study 5- Cytotoxic drug during study 6- Glatiramer acetat ingestion during study

Age
From **3 years** old to **55 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **65**

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
Ethics committee of Ahvaz Jundishapour University of Medical Science

Street address
Golestan St.

City
Ahvaz

Postal code
81336-55676

Approval date
2010-11-21, 1389/08/30

Ethics committee reference number
Eth091

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
fatigue scale

Timepoint
before intervention and one month after beginning of intervention

Method of measurement
fatigue scale of the patient of multiple sclerosis as a questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Control group: who took placebo (placebo was capsules like Boswellia capsules filled with starch)

Category
Treatment - Drugs

2

Description
Intervention group 1: fish liver oil (1500mg per day) produced by USA

Category
Treatment - Drugs

3

Description
Intervention group 2: boswellia (900mg per day). These capsules were synthesized in Ahvaz Pharmacology University. Method of synthesis was concentration of Boswellia Hydroalcoholic solution

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Multiple sclerosis Society of Khoozestan

Full name of responsible person
Nastaran Madjdinasab, Salman Fatemi

Street address
Rehabilitation college of Ahvaz Jundishapor University of Medical Science of

City
Ahvaz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Ahvaz Jondishapour University of Medical Science
Full name of responsible person
Dr Feghhi
Street address
Ahvaz ,Golestan St.
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, Ahvaz Jondishapour University of Medical Science
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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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