

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 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

Country

Iran (Islamic Republic of)

Phone

+98 61 1335 1298

Email address

fatemi.salman@ajums.ac.ir

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 Fegghi

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**

Ahvaz Jundishapour University of Medical Science

Full name of responsible person

Salman Fatemi

Position

Resident of Neurology

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Web page address

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