

# 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

**Other areas of specialty/work****Street address**

Building Eram 2, between Azar and Dey St., Khordad  
St.

**City**

Ahvaz

**Postal code**

81336-13655

**Phone**

+98 61 1335 1298

**Fax****Email**

fatemi.salman@yahoo.com

**Web page address**

## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Ahvaz Jundishapour University of Medical Science

**Full name of responsible person**

Salman Fatemi

**Position**

Resident of Neurology

**Other areas of specialty/work****Street address**

Building Eram 2, Between Azar and Dey, Khordad St.

**City**

Ahvaz

**Postal code**

81336-13655

**Phone**

+98 61 1335 1298

**Fax****Email**

fatemi.salman@yahoo.com

**Web page address**

## Person responsible for updating data

**Contact****Name of organization / entity**

Ahvaz Jundishapour University of Medical Science

**Full name of responsible person**

Salman Fatemi

**Position**

Resident of Neurology

**Other areas of specialty/work****Street address**

Building Eram 2, between Azad and Dey, Khordad St.

**City**

Ahvaz

**Postal code**

81336-55676

**Phone**

+98 61 1335 1298

**Fax****Email**

fatemi.salman@yahoo.com

**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*