

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### Comparison of the effect of liposomal form of pistachio kernel oil and placebo on the level of some inflammatory and anti-inflammatory agents as well as their receptors in mononuclear cells in peripheral blood and change in the severity of clinical symptoms in women with multiple sclerosis

#### Protocol summary

##### Study aim

Comparison of the effect of liposomal form of pistachio kernel oil and placebo on inflammatory and anti-inflammatory agents and their receptors in peripheral blood mononuclear cells and the severity of clinical symptoms in women with multiple sclerosis

##### Design

Clinical trial with control group, double-blind, simple randomized, phase 3 on 500 MS patients. Excel software rand function is used for randomization

##### Settings and conduct

This clinical trial will be performed on MS patients referred to Ali Ibn Abitaleb Hospital in Rafsanjan. 500 MS patients will be included in the study and will be divided into intervention and control groups and will be treated and monitored for 24 weeks with the liposomal form of 10% pistachio kernel oil or placebo. In this study, blinding is also performed. Participants, lead researcher, health care staff responsible for patient care, data collection and outcome assessors, data safety and monitoring committee, and drafters, will keep blind.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Women aged 18 to 51 years with definitive diagnosis of multiple sclerosis and descriptive measurement of disability between 1 to 3. Exclusion criteria: using corticosteroids during study, pregnancy and lactation, autoimmune diseases, other neurological diseases.

##### Intervention groups

Nanoliposome intervention group: This group is given the liposomal form of 10% pistachio kernel oil orally to MS patients for 24 weeks. Control group: This group of placebo is given orally to MS patients for 24 weeks.

##### Main outcome variables

Concentration of inflammatory and anti-inflammatory factors; Relative expression of receptors genes of inflammatory and anti-inflammatory agents; The length and severity of the disease

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20201219049765N1**

Registration date: **2021-08-04, 1400/05/13**

Registration timing: **prospective**

Last update: **2021-08-04, 1400/05/13**

Update count: **0**

##### Registration date

2021-08-04, 1400/05/13

##### Registrant information

##### Name

ali Jebali

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 35 3833 0756

##### Email address

alijebal2011@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-08-19, 1400/05/28

**Expected recruitment end date**

2022-08-19, 1401/05/28

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of the effect of liposomal form of pistachio kernel oil and placebo on the level of some inflammatory and anti-inflammatory agents as well as their receptors in mononuclear cells in peripheral blood and change in the severity of clinical symptoms in women with multiple sclerosis

**Public title**

The effect of consuming the liposomal form of pistachio kernel oil on multiple sclerosis

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Women aged 18 to 51 years Definite diagnosis of multiple sclerosis with a descriptive measure of disability rate between 1 to 3

**Exclusion criteria:**

Taking corticosteroids during the study Pregnancy and lactation Active cardiovascular disease, liver disease, gastrointestinal disease, patients with Helicobacter pylori positive test, kidney disease, diabetes mellitus, respiratory disease and autoimmune diseases Take multivitamin, mineral, antioxidant and pistachio kernel supplements during the 30 days before the study

**Age**

From **18 years** old to **51 years** old

**Gender**

Female

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

**Sample size**

Target sample size: **500**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization method and description of each method: Simple randomization Randomization unit: individual Randomization tool: Excel software How to build a random sequence: with RAND function in excel software Allocation concealment: For allocation concealment, the method of Sequentially numbered, sealed, opaque envelopes (SNOSE) will be used.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Participants, lead researcher, healthcare staff responsible for patient care, data collection and outcome assessors, data safety and monitoring committee, and drafters, They will keep blind. To simulate the intervention in 2 groups, similar vials in terms of volume, shape and appearance will be used.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Rafsanjan University of Medical Sciences

**Street address**

Rafsanjan - Imam Ali Boulevard - Central University Organization - Postal Code: 7717933777

**City**

Rafsanjan

**Province**

Kerman

**Postal code**

7717933777

**Approval date**

2020-10-24, 1399/08/03

**Ethics committee reference number**

IR.RUMS.REC.1399.184

**Health conditions studied****1****Description of health condition studied**

Multiple Sclerosis (MS)

**ICD-10 code**

G35

**ICD-10 code description**

Multiple sclerosis

**Primary outcomes****1****Description**

Concentration of inflammatory and anti-inflammatory factors

**Timepoint**

Intervention time (w0), 6 weeks after intervention (w6), 12 weeks after intervention (w12), 18 weeks after intervention (w18) and 24 weeks after intervention (w24)

## Method of measurement

With ELISA Kit

## 2

### Description

Relative expression of genes of receptors of inflammatory and anti-inflammatory agents

### Timepoint

Intervention time (w0), 24 weeks after intervention (w24)

### Method of measurement

By Realtime PCR

## 3

### Description

The length and severity of the disease

### Timepoint

Intervention time (w0), 6 weeks after intervention (w6), 12 weeks after intervention (w12), 18 weeks after intervention (w18) and 24 weeks after intervention (w24)

### Method of measurement

According to the descriptive measurement of disability rate

## Secondary outcomes

## 1

### Description

Allergies to pistachio compounds

### Timepoint

Intervention time (w0), 6 weeks after intervention (w6), 12 weeks after intervention (w12), 18 weeks after intervention (w18) and 24 weeks after intervention (w24)

### Method of measurement

Qualitative examination with patient self-declaration

## Intervention groups

## 1

### Description

Intervention group: once a day, 5 ml, liposomal form of 10% pistachio kernel oil, orally, for 24 weeks. In this study, no special equipment is used and the explanations of this trial are given in printed form to the volunteers. Of course, entering this study does not require special training. The liposomal form of pistachio kernel oil is also prepared and approved by the Research Institute of Basic Medical Sciences of Rafsanjan University of Medical Sciences.

### Category

Treatment - Drugs

## 2

### Description

Control group: This group will be given the same as the placebo test group with the same intervention group program. In this study, no special equipment is used and the explanations of this trial are given in printed form to

the volunteers. Of course, entering this study does not require special training. Pharmacopoeia is also prepared and approved by the Research Institute of Basic Medical Sciences of Rafsanjan University of Medical Sciences.

### Category

Placebo

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Rafsanjan Ali Ibn Abitaleb Hospital

#### Full name of responsible person

Dr. Gholam Hossein Hassan Shahi

#### Street address

Rafsanjan - Mofteh Boulevard - Hazrat Ali Ibn Abitaleb Hospital

#### City

Rafsanjan

#### Province

Kerman

#### Postal code

7717933777

#### Phone

+98 34 3428 0001

#### Email

alijebal2011@gmail.com

#### Web page address

<http://aliebn.rums.ac.ir/>

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Rafsanjan University of Medical Sciences

#### Full name of responsible person

Dr. Gholam Hossein Hassan Shahi

#### Street address

Address: Rafsanjan - Imam Ali Boulevard - Central Organization

#### City

Rafsanjan

#### Province

Kerman

#### Postal code

7717933777

#### Phone

+98 34 3428 0038

#### Email

alijebal2011@gmail.com

#### Web page address

<http://www.rums.ac.ir/>

#### Grant name

#### Grant code / Reference number

99099

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

Yes

**Title of funding source**  
Rafsanjan University of Medical Sciences  
**Proportion provided by this source**  
100  
**Public or private sector**  
Public  
**Domestic or foreign origin**  
Domestic  
**Category of foreign source of funding**  
*empty*  
**Country of origin**  
**Type of organization providing the funding**  
Academic

## Person responsible for general inquiries

**Contact**  
**Name of organization / entity**  
Rafsanjan University of Medical Sciences  
**Full name of responsible person**  
Dr. Gholam Hossein Hassan Shahi  
**Position**  
full professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Immunology  
**Street address**  
Address: Rafsanjan - Imam Ali Boulevard - Central  
Organization  
**City**  
Rafsanjan  
**Province**  
Kerman  
**Postal code**  
7717933777  
**Phone**  
+98 34 3428 0038  
**Email**  
alijebal2011@gmail.com  
**Web page address**  
<http://www.rums.ac.ir>

## Person responsible for scientific inquiries

**Contact**  
**Name of organization / entity**  
Rafsanjan University of Medical Sciences  
**Full name of responsible person**  
Ali Jebali  
**Position**  
Researcher  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Medical Nanotechnology  
**Street address**  
No2, Yaqut building, anbiya shomali Blvd, Yazd  
**City**  
Yazd  
**Province**

Yazd  
**Postal code**  
8915897671  
**Phone**  
+98 35 3833 0756  
**Fax**  
**Email**  
alijebal2011@gmail.com

## Person responsible for updating data

**Contact**  
**Name of organization / entity**  
Rafsanjan University of Medical Sciences  
**Full name of responsible person**  
Ali Jebali  
**Position**  
Researcher  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Medical Nanotechnology  
**Street address**  
No2, Yaqut building, anbiya shomali Blvd, Yazd  
**City**  
Yazd  
**Province**  
Yazd  
**Postal code**  
8915897671  
**Phone**  
+98 35 3833 0756  
**Fax**  
**Email**  
alijebal2011@gmail.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**  
Yes - There is a plan to make this available  
**Study Protocol**  
Yes - There is a plan to make this available  
**Statistical Analysis Plan**  
Yes - There is a plan to make this available  
**Informed Consent Form**  
Yes - There is a plan to make this available  
**Clinical Study Report**  
Yes - There is a plan to make this available  
**Analytic Code**  
Yes - There is a plan to make this available  
**Data Dictionary**  
Yes - There is a plan to make this available  
**Title and more details about the data/document**  
Information on primary and secondary outcomes will be available to researchers  
**When the data will become available and for how long**  
Infinitely after the publication of the article  
**To whom data/document is available**  
Researchers and volunteers surveyed  
**Under which criteria data/document could be used**  
For research work

**From where data/document is obtainable**

Responsible of the project Gholamhossein Hasanshahi  
alijebal2011@gmail.com

**What processes are involved for a request to access**

**data/document**

Formal request to the university and then refer to the  
project manager

**Comments**