Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
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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
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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
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Person responsible for updating data

Contact
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Ph.D.
Other areas of specialty/work
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8915897671
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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