Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Evaluation of the garlic extract (Allium sativum) effect to improving fatigue and quality of life in patients with multiple sclerosis (MS) a randomized, placebo-controlled clinical trial

Protocol summary

Study aim
Evaluation of the garlic extract (Allium sativum) effect to improving fatigue and quality of life in patients with multiple sclerosis (MS)

Design
clinical trial with control group, parallel groups, double-blind, randomized

Settings and conduct
This study will be performed in the MS clinic of Al-Zahra Hospital and Ayatollah Kashani Hospital affiliated to Isfahan University of Medical Sciences. For the drug group, garlic tablets (produced by Amin Pharmaceutical Company called Garlet, which contains 400 mg of garlic extract powder and standardized based on 1200 micrograms of allicin and equivalent to 2 grams of fresh garlic) at a dose of 400 mg every 12 hours for 4 weeks and For people in the placebo group, the placebo pill (produced by the same company with the same shape and packing) will be prescribed with the same frequency and duration. Patients in both groups will receive their standard treatment according to the opinion and prescription of the plan's doctor (neurologist). Patients will fill in the questionnaires before the start and end of the study.

Participants/Inclusion and exclusion criteria
Age over 18 years/ Relapsing-remitting MS/ At least 6 months have passed since the diagnosis/ Advanced Disability Status Scale (EDSS) ≤ 5/ Complaints of obvious fatigue No entry: Pregnancy/ Breastfeeding/ Diseases causing fatigue/ Having diseases that cause fatigue such as diabetes/ Use of psychotropic drugs, effective antidepressants

Intervention groups
Drug group : Garlic tablets (produced by Amin Pharmaceutical Company called Garlet, which contains 400 mg of garlic extract powder and standardized based on 1200 micrograms of allicin and equivalent to 2 grams of fresh garlic) at a dose of 400 mg every 12 hours for 4 weeks Placebo group: Placebo tablets (produced by the same company with similar shape and packaging)

Main outcome variables
severity of fatigue and increase life quality

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150721023282N15**
Registration date: **2021-03-01, 1399/12/11**
Registration timing: **retrospective**

Last update: **2021-03-01, 1399/12/11**
Update count: **0**

Registration date
2021-03-01, 1399/12/11

Registrant information

Name
Rasool Soltani

Name of organization / entity
Isfahan University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 31 3792 7067

Email address
soltani@pharm.mui.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-11-29, 1399/09/09

Expected recruitment end date

2020-12-05, 1399/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the garlic extract (Allium sativum) effect to improving fatigue and quality of life in patients with multiple sclerosis (MS) a randomized, placebo-controlled clinical trial

Public title

The effect of garlic on fatigue and quality of life in MS patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Relapsing-remitting MS At least 6 months have passed since the diagnosis Complaints of obvious fatigue

Exclusion criteria:

Pregnancy Breastfeeding Diseases causing fatigue acute recurrence stage

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization method using blocks of size 4 will be used. So that all possible sequences of two drug and two placebo in each block will be made with each block being numbered. Then, using random number table, the blocks will be selected randomly and the patients will be assigned to the two groups of drug and placebo according to the the blocks sequences.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients, the prescribing physician and the data analyst will be blind to the intervention type. The drug and placebo will be prepared in similar coded bottles and given to the chief researcher. A bottle will be given to each patient according to the chief researcher.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Isfahan University of Medical Sciences

Street address

Hezar-Jerib Ave.

City

Isfahan

Province

Isfehan

Postal code

8174673461

Approval date

2020-07-10, 1399/04/20

Ethics committee reference number

IR.MUI.RESEARCH.REC.1399.420

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 severity

Timepoint

Before and after the intervention

Method of measurement

fatigue severity sacle (fss)

2

Description

Quality of life

Timepoint

Before and after the intervention

Method of measurement

The Short Form Health Survey (SF-36)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Allium 400-mg tablets (manufactured by Amin company), every 12 hours, for 4 weeks
Category
Treatment - Drugs

2

Description
Placebo group: Placebo tablets (manufactured by Amin company), every 12 hours, for 4 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
MS clinic of Al-Zahra hospital
Full name of responsible person
Rasool Soltani
Street address
Soffeh Ave
City
Isfahan
Province
Isfehan
Postal code
8174675731
Phone
+98 31 3620 2020
Fax
Email
alzahra@mui.ac.ir
Web page address
http://alzahra.mui.ac.ir

2

Recruitment center
Name of recruitment center
clinic of Ayatollah Kashani Hospital
Full name of responsible person
Rasool Soltani
Street address
Kashani St
City
Isfahan
Province
Isfehan
Postal code
۸۳۴۳۴۸۱۸۳۹
Phone
+98 31 3233 0091
Email
soltani@pharm.mui.ac.ir
Web page address
https://kashani.mui.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shaghayegh Haghjooy Javanmard
Street address
Hezar-Jerib Ave
City
Isfahan
Province
Isfehan
Postal code
8174683461
Phone
+98 31 3792 3071
Email
research@mui.ac.ir
Web page address
http://mui.ac.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Rasool Soltani
Position
Associate Professor
Latest degree
Specialist
Other areas of specialty/work
Medical Pharmacy
Street address
Hezar-Jerib Ave.
City
Isfahan
Province
Isfehan
Postal code

8176776161

Phone
+98 31 3786 5537

Email
soltani@pharm.mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Rasool Soltani

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Medical Pharmacy

Street address
Hezar-Jerib Ave.

City
Isfahan

Province
Isfehan

Postal code
8176776161

Phone
+98 31 3786 5537

Email
soltani@pharm.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Rasool Soltani

Position
Associate professor

Latest degree
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Other areas of specialty/work
Medical Pharmacy

Street address
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8174673461

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Email
soltani@pharm.mui.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
Confidentiality of patients data

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available