# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Nov 2026

## Investigation of the effects of oral consumption of Lepidium sativum L. seed on sexual dysfunction in female patients with multiple sclerosis: A randomized double-blind placebo-control clinical trial

## Protocol summary


**Study aim**

Determination of the Effectiveness of an Oral Product Containing Cress Seeds on Improving Sexual Dysfunction in Female Patients with Multiple Sclerosis (MS) as a Clinical Trial Study.

**Design**

This is a phase II, randomized, double-blind, placebo-controlled, parallel-group clinical trial involving 68 patients. Randomization will be performed using the 'Random Allocation 2' statistical software.

**Settings and conduct**

One gram capsule is prepared from Cress seed powder. Standardization and physicochemical control of the product is done in the Faculty of Pharmacy. Subsequently, a double-blind randomized clinical trial will be performed at the MS clinic of Bu-Ali Sina Sari Educational Center involving 34 patients over the age of 18 in each group called the intervention group (capsules containing Cress seed) and control (capsules containing starch); Patients meeting the MCDonald 2017 criteria with an EDSS score of less than 5.5 and an MSISQ-19 score higher than 27 after MS Fellowship and obtaining consent are entered into the study. By observing the apparent similarity of the drug products, the patient receiving the drug and the researcher evaluating the study variables and the prescribing neurologist are not aware of the type of drug received.

**Participants/Inclusion and exclusion criteria**

Inclusion Criteria: Patients with multiple sclerosis aged over 18 years, presenting with an EDSS score of less than 5.5 and sexual dysfunction indicated by an MSISQ-19 score greater than 27. Exclusion Criteria: Patients with severe depression, hypothyroidism, diabetes, history of seizures

**Intervention groups**

Patients will be block-randomized to receive either oral capsules containing powdered cress seeds or a placebo for a period of 12 weeks. The study medication will be administered as 1-gram capsules taken twice daily.

**Main outcome variables**

Patients quality of life, sexual function status


## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20160913029802N5**
Registration date: **2026-04-22, 1405/02/02**
Registration timing: **prospective**

Last update: **2026-04-22, 1405/02/02**
Update count: **0**

**Registration date**

2026-04-22, 1405/02/02

**Registrant information**


**Name**

Somayeh Shahani

**Name of organization / entity**

Mazandaran University of Medical Sciences

**Country**

Iran (Islamic Republic of)

**Phone**

+98 11 3354 3761

**Email address**

s.shahani@mazums.ac.ir


**Recruitment status**

**recruiting**

**Funding source**

**Expected recruitment start date**

2026-06-05, 1405/03/15

**Expected recruitment end date**

2027-02-04, 1405/11/15

**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Investigation of the effects of oral consumption of Lepidium sativum L. seed on sexual dysfunction in female patients with multiple sclerosis: A randomized double-blind placebo-control clinical trial

**Public title**
Investigation of the Effect of Oral Consumption of Cress Seed on Sexual Dysfunction in Female Patients with Multiple Sclerosis
**Purpose**
Supportive
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Adults aged 18 years and older diagnosed with multiple sclerosis, according to the 2015 McDonald criteria, with an EDSS score of less than 5.5. Sexually active in the past six months and experiencing sexual problems, with an MSISQ-19 score above 27.
**Exclusion criteria:**
Severe depression assessed using the HADS questionnaire (score of 11 or higher) Hypothyroidism Untreated anemia History of seizures Diabetes History of bulimia nervosa or anorexia nervosa Presence of a known severe psychiatric disorder Pregnancy or breastfeeding Exposure to major crises, such as the death of close relatives, in the past six months Genitourinary environmental problems
**Age**
From **18 years** old
**Gender**
Female

**Phase**
2-3
**Groups that have been masked**

- Participant
- Care provider
- Investigator

**Sample size**
Target sample size: **68**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
For the allocation of participants into two groups, a randomized block method will be used. For this purpose, participants will be randomly assigned numbers from 1 to 68. The randomization unit will be individual, using blocks of four. The group assignment for each participant will be determined using the statistical software Random Allocation 2. To generate the random sequence, codes A and B will be produced by the software. The codes will then be placed in sealed envelopes, with each envelope labeled with the participant's number. The research team will open the envelopes, and if the code is A, the participant will be assigned to the drug group; if the code is B, the participant will be assigned to the placebo group.
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
The visual similarity between the drug-containing capsules and the placebo will be ensured, and both will be placed in identical, coded drug packages according to the randomization table. Each code will correspond to a specific participant. Neither the patients receiving the medication, the pharmacy student assessing the study variables, nor the prescribing neurologist will be aware of the type of drug administered. In the event of any serious adverse effect following the prescribed product, the participant's code will be unblinded. It should be noted that the principal investigator of the study is aware of the randomization codes.
**Placebo**
Used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics committee of Mazandaran University of Medical Sciences
**Street address**
Vice Chancellor for Research and Technology, Moallem Square
**City**
Sari
**Province**
Mazandaran
**Postal code**
4817844718
**Approval date**
2026-02-21, 1404/12/02
**Ethics committee reference number**
IR.MAZUMS.REC.1404.619

## Health conditions studied

### 1

**Description of health condition studied**
Multiple Sclerosis
**ICD-10 code**
G35
**ICD-10 code description**
Multiple sclerosis

**2**

**Description of health condition studied**
Sexual dysfunction associated with multiple sclerosis
**ICD-10 code**
F66
**ICD-10 code description**
Other sexual disorders

## Primary outcomes

**1**

**Description**
Sexual dysfunction
**Timepoint**
At baseline, and at 6 and 12 weeks after the start of treatment
**Method of measurement**
The 19-item Multiple Sclerosis Intimacy and Sexuality Questionnaire (MSISQ-19)

## Secondary outcomes

**1**

**Description**
Multiple Sclerosis Quality Of Life
**Timepoint**
At baseline, and at 6 and 12 weeks after initiation of treatment
**Method of measurement**
Multiple Sclerosis Quality Of Life 54(MSQOL-54) score

## Intervention groups

**1**

**Description**
Intervention group: Participants receiving the oral product containing powdered cress seeds prepared in the Pharmacognosy and Pharmaceutics laboratories of the Faculty of Pharmacy, Sari. The product will be administered twice daily at a dose of 1 gram per dose. The duration of treatment will be 12 weeks.
**Category**
Lifestyle

**2**

**Description**
Control group: The control group will receive capsules containing starch, prepared in the Pharmaceutics Laboratory of the Faculty of Pharmacy, Sari. The product will be administered twice daily at a dose of 1 gram per dose. The duration of treatment will be 12 weeks.
**Category**
Placebo

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
The MS Clinic of Bu-Ali Sina Educational and Therapeutic Center, Sari.
**Full name of responsible person**
Monireh Ghazaeian
**Street address**
Pasdaran Boulevard, Bu-Ali Sina Hospital.
**City**
sari
**Province**
Mazandaran
**Postal code**
4815838477
**Phone**
+98 11 3334 3014
**Fax**
+98 11 3334 4507
**Email**
ghazaeianm@gmail.com
**Web page address**

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Mazandaran University of Medical Sciences
**Full name of responsible person**
Ahmad Ali Enayati
**Street address**
Vice chancellor for Research and Technology, Moallem St, Moallem Sq.
**City**
sari
**Province**
Mazandaran
**Postal code**
4817844718
**Phone**
+98 11 3325 7230
**Fax**
+98 11 3325 7230
**Email**
A.enayati@mazums.ac.ir
**Web page address**
https://research.mazums.ac.ir
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Mazandaran 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**
Mazandaran University of Medical Sciences
**Full name of responsible person**
Monireh Ghazaeian
**Position**
Assistant Professor
**Latest degree**
Ph.D.
**Other areas of specialty/work**
Clinical Pharmacist
**Street address**
Faculty of Pharmacy, Mazandaran University of Medical Sciences, , Farahabad Road
**City**
sari
**Province**
Mazandaran
**Postal code**
4847193698
**Phone**
+98 11 3354 3082
**Fax**
**Email**
ghazaeianm@gmail.com

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Mazandaran University of Medical Sciences
**Full name of responsible person**
Somayeh Shahani
**Position**
Associate Professor
**Latest degree**
Ph.D.
**Other areas of specialty/work**
Medical Pharmacy
**Street address**
Faculty of Pharmacy, Mazandaran University of Medical Sciences, Farahabad Road
**City**
sari
**Province**
Mazandaran
**Postal code**
4847193698
**Phone**
+98 11 3354 3082
**Email**
so.shahani@yahoo.com

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Mazandaran University of Medical Sciences
**Full name of responsible person**
Somayeh Shahani
**Position**
Associate Professor
**Latest degree**
Ph.D.
**Other areas of specialty/work**
Medical Pharmacy
**Street address**
Faculty of Pharmacy, Mazandaran University of Medical Sciences, Farahabad Road
**City**
sari
**Province**
Mazandaran
**Postal code**
4847193698
**Phone**
+98 11 3354 3082
**Email**
so.shahani@yahoo.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Undecided - It is not yet known if there will be a plan to make this available
**Study Protocol**
Undecided - It is not yet known if there will be a plan to make this available
**Statistical Analysis Plan**
Undecided - It is not yet known if there will be a plan to make this available
**Informed Consent Form**
Undecided - It is not yet known if there will be a plan to make this available
**Clinical Study Report**
Undecided - It is not yet known if there will be a plan to make this available
**Analytic Code**
Undecided - It is not yet known if there will be a plan to make this available
**Data Dictionary**
Undecided - It is not yet known if there will be a plan to make this available