

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Sep 2026

### Effect of anti-inflammatory diet on inflammatory markers , oxidative stress , disability, fatigue and quality of life in relapsing-remitting multiple sclerosis patient

#### Protocol summary

##### Study aim

Effect of anti-inflammatory diet on inflammatory markers, oxidative stress, disability, fatigue and quality of life in relapsing-remitting multiple sclerosis patient

##### Design

In this clinical trial with parallel groups , 120 eligible relapsing-remitting multiple sclerosis patients will be chosen. Then participants will randomly divided to intervention and control groups and a code will be assigned to each of them

##### Settings and conduct

Intervention group , antiinflammatory diet based on antiinflammatory diet pyramid and control group will received healthy diet recommendations. This study will be conducted in MS research center affiliated to Shiraz University of Medical Sciences.

##### Participants/Inclusion and exclusion criteria

Age 20-40 years; EDSS <5.5; Voluntary cooperation; Clinical course of relapsing-remitting; Use of a particular diet during the last 3 months before entering the study

##### Intervention groups

Relapsing-remitting multiple sclerosis patients

##### Main outcome variables

Change in disability score ( EDSS ) ; change in fatigue score (MFIS) ; change in quality of life ( MSQOL-54 ) ; change in IL17 ; change in IL4 ; change in hs-CRP

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20171217037916N2**

Registration date: **2018-09-05, 1397/06/14**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-09-05, 1397/06/14**

Update count: **0**

##### Registration date

2018-09-05, 1397/06/14

##### Registrant information

###### Name

Zahra Mousavi Shirazi Fard

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 3628 1540

###### Email address

z\_mousavi@sums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

##### Expected recruitment start date

2018-07-22, 1397/04/31

##### Expected recruitment end date

2019-01-19, 1397/10/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of anti-inflammatory diet on inflammatory markers , oxidative stress , disability, fatigue and quality of life in relapsing-remitting multiple sclerosis patient

##### Public title

Effect of diet on multiple sclerosis patient

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

**Inclusion criteria:**  
 Age 20-50 years EDSS<5.5 Voluntary cooperation  
 Clinical course of relapse-remitting

**Exclusion criteria:**  
 Use of a particular diet during the last 3 months before entering the study

**Age**  
 From **20 years** old to **50 years** old

**Gender**  
 Both

**Phase**  
 N/A

**Groups that have been masked**  
*No information*

**Sample size**  
 Target sample size: **120**

**Randomization (investigator's opinion)**  
 Randomized

**Randomization description**  
 Block randomization

**Blinding (investigator's opinion)**  
 Not blinded

**Blinding description**

**Placebo**  
 Not used

**Assignment**  
 Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

##### Street address

Central building of Shiraz University of Medical Sciences , Zand St.

##### City

Shiraz

##### Province

Fars

##### Postal code

71348-14336

#### Approval date

2018-05-08, 1397/02/18

#### Ethics committee reference number

IR.SUMS.REC.1397.140

## 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

Disability

#### Timepoint

Before intervention and 12 weeks after intervention

#### Method of measurement

Expanded disability status scale

### 2

#### Description

Fatigue

#### Timepoint

Before intervention and 12 weeks after intervention

#### Method of measurement

Modified fatigue impact scale

### 3

#### Description

Quality of life

#### Timepoint

Before intervention and 12 weeks after intervention

#### Method of measurement

Multiple Sclerosis Questionnaire of Life-54

### 4

#### Description

hs-CRP

#### Timepoint

Before intervention and 12 weeks after intervention

#### Method of measurement

Laboratory kit

### 5

#### Description

IL17

#### Timepoint

Before intervention and 12 weeks after intervention

#### Method of measurement

ELISA

### 6

#### Description

IL4

#### Timepoint

Before intervention and 12 weeks after intervention

#### Method of measurement

ELISA

## Secondary outcomes

### 1

**Description**

Total antioxidant capacity

**Timepoint**

Before intervention and 12 weeks after intervention

**Method of measurement**

Laboratory kit

### 2

**Description**

Glutathione

**Timepoint**

Before intervention and 12 weeks after intervention

**Method of measurement**

Laboratory kit

### 3

**Description**

Malondialdehyde

**Timepoint**

Before intervention and 12 weeks after intervention

**Method of measurement**

Laboratory kit

## Intervention groups

### 1

**Description**

Intervention group: anti-inflammatory diet

**Category**

Lifestyle

### 2

**Description**

Control group: healthy diet recommendation

**Category**

Lifestyle

## Recruitment centers

### 1

**Recruitment center****Name of recruitment center**

مرکز تحقیقات ام اس

**Full name of responsible person**

Dr. Sadegh Izadi

**Street address**

Chamran hospital , Chamran Blvd., Shiraz

**City**

Shiraz

**Province**

Fars

**Postal code**

71347-14335

**Phone**

+98 71 3623 4507

**Email**

shirazifard1393@gmail.com

## Sponsors / Funding sources

### 1

**Sponsor****Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Dr. Basir Hashemi

**Street address**

Central building of Shiraz University of Medical Sciences , Zand St., Shiraz

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Shiraz

**Province**

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**Phone**

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**Email**

hashemib@sums.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Shiraz 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**

Shiraz University of Medical Sciences

**Full name of responsible person**

Dr. zohreh Mazloom

**Position**

Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

**Street address**

School of Nutrition and Food Sciences, Razi s.t, Shiraz

**City**

Shiraz  
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**Postal code**  
7153675541  
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+98 71372510015  
**Email**  
z\_mousavi@sums.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Shiraz University of Medical Sciences  
**Full name of responsible person**  
Dr. Zohreh Mazloom  
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Professor  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Shiraz University of Medical Sciences  
**Full name of responsible person**  
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**Position**  
Ph.D student  
**Latest degree**  
Master  
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**Postal code**  
7153675541  
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+98 71372510015  
**Email**  
z\_mousavi@sums.ac.ir

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

### Title and more details about the data/document

Information about the assessment of disability, fatigue and quality of life after the unidentifiable participant is unobtrusiv

### When the data will become available and for how long

Start the access period 6 months after printing the results

### To whom data/document is available

Study data will only be available to researchers working in academic and academic institutions

### Under which criteria data/document could be used

Use in meta-analysis

### From where data/document is obtainable

Dr.Zohreh Mazloom , zohreh.mazloom@gmail.com ,  
Zahra Mousavi , shirazifard1393@gmail.com

### What processes are involved for a request to access data/document

Sending information about personal details, sending workplace information, sending information about the reason for requesting data

### Comments