Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
City
Shiraz
Province
Fars
Postal code
71348-14336
Phone
+98 71 3235 7282
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
Province
Fars
Postal code
7153675541
Phone
+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
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
Province
Fars
Postal code
7153675541
Phone
+98 71372510015
Email
z_mousavi@sums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Zahra Mousavi Shirazi Fard
Position
Ph.D student
Latest degree
Master
Other areas of specialty/work
Nutrition
Street address
School of Nutrition and Food Sciences, Razi s.t, Shiraz
City
Shiraz
Province
Fars
Postal code
7153675541
Phone
+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