

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of Clinical and Metabolic Responses to Combined Effect of Curcumin, Cholecalciferol, and Evening Primrose oil in Patients with Multiple Sclerosis

Protocol summary

Study aim

Determination of Clinical and Metabolic Responses to the combined Effect of Curcumin, Cholecalciferol and Olive Oil in Patients with Multiple Sclerosis

Design

Random assignment was done by the use of computer-generated random numbers. Population and sample size: In the study 60 patients with Multiple Sclerosis among males and females of eligible and referred to health and clinical centers affiliated to Qazvin University of Medical Sciences, Qazvin, Iran, were selected.

Settings and conduct

In the study 60 patients with Multiple Sclerosis among males and females of eligible and referred to health and clinical centers affiliated to Qazvin University of Medical Sciences, Qazvin, Iran, were selected. Patients and researchers are blind until the end of the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: subjects with Multiple Sclerosis.
Exclusion criteria: patients who did not want to cooperate; patients who had others complications such as: kidney disease, neuropathy and retinopathy, patients with hypo and/or hyperthyroidism and so patients with other inflammatory diseases such as allergies and autoimmune diseases, and pregnant women were excluded from this study.

Intervention groups

Patients were assigned to receive either extract (intervention group: n=30) or placebo (control group: n=30).

Main outcome variables

Clinical and Metabolic Responses in Patients with Multiple Sclerosis were measured before and after of the intervention.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170430033730N6**

Registration date: **2019-03-25, 1398/01/05**

Registration timing: **prospective**

Last update: **2019-03-25, 1398/01/05**

Update count: **0**

Registration date

2019-03-25, 1398/01/05

Registrant information

Name

Seyyed Mehdi Mirhashemi

Name of organization / entity

Qazvin University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-13, 1398/01/24

Expected recruitment end date

2019-05-02, 1398/02/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation of Clinical and Metabolic Responses to Combined Effect of Curcumin, Cholecalciferol, and Evening Primrose oil in Patients with Multiple Sclerosis

Public title
Effect of Curcumin, Vitamin D and herbal oil on Multiple Sclerosis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients with MS
Exclusion criteria:
Patients who do not want to cooperate; Patients who have others complications such as: kidney disease; neuropathy and retinopathy; Patients with hypo and/or hyperthyroidism are excluded from this study. Patients with other inflammatory conditions such as allergies and autoimmune diseases pregnant women

Age
From **20 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization, Random assignment was done by the use of computer-generated random numbers.

Blinding (investigator's opinion)
Double blinded

Blinding description
A placebo was used to blind. Researchers and Patients will be blinded by the professional analyst until final analysis.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Qazvin University of Medical

Sciences

Street address
Qazvin University of Medical Sciences, Shahid Bahonar Blvd

City
Qazvin

Province
Qazvin

Postal code
3419759811

Approval date
2019-02-21, 1397/12/02

Ethics committee reference number
IR. QUMS. REC.1397.351

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

hs-CRP

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

Elisa

2

Description

IL-18

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

Elisa

Secondary outcomes

1

Description

T25FW test

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

Physical examination

2

Description

9-HPT Test

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

Physical examination

3

Description

FBS

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

Spectrophotometry

4

Description

Insulin

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

ELISA

5

Description

TG

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

Spectrophotometry

6

Description

Cholesterol

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

Spectrophotometry

7

Description

HDL

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

Spectrophotometry

8

Description

LDL

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

Spectrophotometry

9

Description

AST

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

Spectrophotometry

10

Description

ALT

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

Spectrophotometry

11

Description

ALKP

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

Spectrophotometry

12

Description

TP

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

Spectrophotometry

13

Description

Alb

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

Spectrophotometry

14

Description

BUN

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

Spectrophotometry

15

Description

کراتین

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

Spectrophotometry

16

Description

Glutathione

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

Spectrophotometry

17

Description

MDA

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

Spectrophotometry

18

Description

SOD

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

Spectrophotometry

19

Description

NO

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

Spectrophotometry

Intervention groups

1

Description

Intervention group: Two sub-gels containing (80 mg curcumin + 1000 IUD3) and Primrose oil (1000 mg) will receive daily for twelve weeks

Category

Treatment - Drugs

2

Description

Control group: Two sub-gels of placebo were taken daily for 12 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Boo-Ali Hospital

Full name of responsible person

Dr Seyyed Mehdi Mirhashemi

Street address

Shahid Bamonar Blvd

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34197 - 59811

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Email

mirhashemism@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Dr Amir Peymani

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Vice Chancellor for research of Qazvin University of Medical Sciences, Shahid Beheshti Blvd, Qazvin

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Qazvin 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
Qazvin University of Medical Sciences
Full name of responsible person
Seyyed Mehdi Mirhashemi
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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

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable