# 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)

**Phone**

+98 28 3333 6001

**Email address**

sm.mirhashemi@qums.ac.ir

**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**
کراتنین
**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 Bahonar Blovard
**City**
Qazvin
**Province**
Qazvin
**Postal code**
34197 - 59811
**Phone**
+98 28 3333 6001
**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
**Street address**
Vice Chancellor for research of Qazvin University of Medical Sciences, Shahid Beheshti Blvd, Qazvin
**City**
Qazvin
**Province**
Qazvin
**Postal code**
34197 - 59811
**Phone**
+98 28 3333 6001
**Email**
a.peymani@gmail.com
**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

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Biochemistry

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Qazvin University of Medical Sciences

**Full name of responsible person**

Seyyed Mehdi Mirhashemi

**Position**

Associate professor

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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