# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

30 May 2026

## The effect of Curcumin on Oxidant , Antioxidant factors ,Liver ,Kidney tests serum , Clinical signs and symptoms of MultipleSclerosis patients

## Protocol summary

**Study aim**
The effect of curcumin on oxidant , antioxidant factors , liver ,kidney tests serum , clinical signs and symptoms of multiple sclerosis patients

**Design**
Clinical practice with control group, parallel, double-blind, randomized, phase 3 over 96 patients, blocked randomization method

**Settings and conduct**
The clinics of Arak University of Medical Sciences will be double-blind and patients will be divided into two groups of cases and Dronoma as blocked randomization with 4 and 6 block sizes. The doctor's secretary (who has no knowledge of the type of capsules and the group of patients in which they are placed) will be given. Thus, the researcher, the specialist, the patient will be blinded.

**Participants/Inclusion and exclusion criteria**
Ms have RRMS, age 18 to 50, and EDSS (less than 4). Patients who have been diagnosed with MS for at least a year have no gastrointestinal problems. Don't take zinc supplements or selenium supplements. Anthocyanin-like corticosteroids, such as vitamin EA-D, haven't been used for at least the past two weeks. Don't be pregnant. Don't be breastfeeding women

**Intervention groups**
Razak 270 mg Corkomine Capsule, Stanoma Pharma Capsule Capsule

**Main outcome variables**
Total Oxidative Capacity, Oxygenated Water, Malondialdehyde, Revitalizing Glutathione, Dysmotaz Super Oxide, Alanine Amino Transfer, Aspartate Amino Transfer, Nitrogen Urea Blood, Blood Creatinine, Fatigue, gait disorders and severe disability

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20200614047766N1**
Registration date: **2020-06-30, 1399/04/10**
Registration timing: **prospective**

Last update: **2020-06-30, 1399/04/10**
Update count: **0**

**Registration date**
2020-06-30, 1399/04/10

**Registrant information**

**Name**
Zahra Godarzi

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

**Phone**
+98 86 3276 3822

**Email address**
kiyangolmohamadi@gmail.com

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2020-09-21, 1399/06/31

**Expected recruitment end date**
2021-02-18, 1399/11/30

**Actual recruitment start date**
2020-09-21, 1399/06/31

**Actual recruitment end date**
2021-02-18, 1399/11/30

**Trial completion date**
2021-06-21, 1400/03/31

**Scientific title**
The effect of Curcumin on Oxidant , Antioxidant factors ,Liver ,Kidney tests serum , Clinical signs and symptoms of MultipleSclerosis patients

**Public title**

Investigation of the effect of curcumin in Multiple Sclerosis

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

The study subjects must have RRMS type Ms disease They are 18 to 50 years old and EDSS (disease incapacity severity) must be less than 4 Patients who have been diagnosed with MS for at least one year Patients who do not have a specific digestive problem (gastric and duodenal ulcers, irritable bowel syndrome, indigestion) Not sensitive to curcumin They do not receive zinc or selenium supplements Antioxidant corticosteroids, such as vitamin E-A-D, have not been used for at least the past two weeks. They are not pregnant Don't be a breastfeeding woman They do not have special liver or kidney problems

**Exclusion criteria:**

Lack of willingness of the patient to continue cooperation patients with mental disorders

**Age**

From **18 years** old to **50 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **96**

Actual sample size reached: **96**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Patients with divided randomization with block sizes of 4 and 6 blocks will be divided into two groups of cases (MS patients who will receive curcumin in 48 people) and Dardonema (MS patients who will receive placebo in 48 people). In this way, we paste 96 randomly selected codes on 96 cans of capsules that are similar in color, shape and size, and after pouring the curcumin capsule and placebo capsule according to the codes in the cans, we put all the cans. Pour into a bag.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

According to the codes we have, Razak's 370 mg curcumin capsules will initially be given twice daily to the CASE group and the placebo-containing placebo capsule to the placebo group by the doctor's secretary (who has no knowledge of the type of capsules or what group of patients are in which). In this way, the doctor, the researcher and the patient have no knowledge of the groups

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethics Committee of Arak University of Medical Sciences

**Street address**

Deputy of Research and Technology, Payambar Azam University Complex, Basij Square, Sardasht St

**City**

Arak

**Province**

Markazi

**Postal code**

3848176341

**Approval date**

2020-06-08, 1399/03/19

**Ethics committee reference number**

IR.ARAKMU.REC1399.068

## Health conditions studied

### 1

**Description of health condition studied**

Multiple Sclerosis

**ICD-10 code**

G35

**ICD-10 code description**

Demyelinating diseases of the central nervous system

## Primary outcomes

### 1

**Description**

Total oxidative status

**Timepoint**

Measurement of total oxidative status at the beginning of the study (before the start of the intervention) and 3 months after the start of use of curcumin capsules

**Method of measurement**

Total Oxidative Status Measurement Kit

### 2

**Description**

Malone Dialdehyde

**Timepoint**

Measurement of malondialdehyde at the beginning of the study (before the intervention) and 3 months after the

start of use of curcumin capsules

**Method of measurement**

Malon dialdehyde Measurement Kit

**3**

**Description**

آب اکسیژنه

**Timepoint**

Measurement of oxygenated water at the beginning of the study (before the start of the intervention) and 3 months after the start of taking curcumin capsules

**Method of measurement**

Oxygenated water measurement kit

**4**

**Description**

Super Oxide Dismutase

**Timepoint**

Measurement of dismutase superoxide at the beginning of the study (before the start of the intervention) and 3 months after the start of taking curcumin capsules

**Method of measurement**

Dysmotase Super Oxide Measurement Kit

**5**

**Description**

Glutathione Revival

**Timepoint**

Measurement of glutathione reductase at the beginning of the study (before the start of the intervention) and 3 months after the start of the use of curcumin capsules

**Method of measurement**

Glutathione Revitalization Measurement Kit

**6**

**Description**

Aspartate amino transferase

**Timepoint**

At the beginning of the study (before the start of the intervention) and 3 months after the start of taking curcumin

**Method of measurement**

Aspartate aminotransferase assay kit

**7**

**Description**

Alanin amino transferase

**Timepoint**

The beginning of the study (before the start of the intervention) and 3 months after the start of taking curcumin

**Method of measurement**

Alanine Amino Transfer Measurement Kit

**8**

**Description**

Blood creatinine

**Timepoint**

At the beginning of the study (before the start of the intervention) and 3 months after the start of taking curcumin

**Method of measurement**

Creatine measuring kit

**9**

**Description**

Nitrogen in the blood urea

**Timepoint**

At the beginning of the study and 3 months after taking curcumin

**Method of measurement**

Blood urea nitrogen measurement kit

## Secondary outcomes

**1**

**Description**

Expanded Disability Status Scale

**Timepoint**

At the beginning of the study (before the start of the intervention) and 3 months after the start of taking curcumin capsules

**Method of measurement**

questionnaire

**2**

**Description**

Fatigue Severity Scale

**Timepoint**

At the beginning of the study (before the start of the intervention) and 3 months after the start of taking curcumin capsules

**Method of measurement**

questionnaire

**3**

**Description**

Gait disorder

**Timepoint**

At the beginning of the study (before the start of the intervention) and 3 months after the start of use of curcumin capsules

**Method of measurement**

25 foot test

## Intervention groups

**1**

**Description**

Intervention group: Intervention group: MS patients who take Corkomine oral capsule for 3 months at a dose of 370 mg, take one a day at the beginning of the study and then take it twice a day. It has high antioxidant properties.

**Category**
Treatment - Drugs

**2**

**Description**
Control group: MS patients who receive placebo for 3 months
**Category**
Placebo

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Kosar Clinic
**Full name of responsible person**
Zahra Goodarzi
**Street address**
No. 3634, Kosar specialized clinic, Seyedha mosque, Imam khomeini st, Arak
**City**
Arak
**Province**
Markazi
**Postal code**
3814113634
**Phone**
+98 86 3223 3823
**Email**
it.kousar@arakmu.ac.ir

**2**

**Recruitment center**
**Name of recruitment center**
Imam Reza Clinic
**Full name of responsible person**
Zahra Goodarzi
**Street address**
No.9589, Shahid Shiroudi St, Arak
**City**
Arak
**Province**
Markazi
**Postal code**
3813899589
**Phone**
+98 86 3240 2002
**Email**
farahaniheidar@yahoo.com

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Arak University of Medical Sciences
**Full name of responsible person**
Alireza Kamali
**Street address**
No.6341, Deputy of Research and Technology, University Complex of the Great Prophet, University of Medical Sciences, Basij Square, Sardasht St. Arak
**City**
Arak
**Province**
Markazi
**Postal code**
3848176341
**Phone**
+98 86 3417 3639
**Email**
research@arakmu.ac.ir
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Arak 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**
Arak University of Medical Sciences
**Full name of responsible person**
Zahra Goodarzi
**Position**
University Student
**Latest degree**
Bachelor
**Other areas of specialty/work**
Biochemistry
**Street address**
No. 9881, 30 Shams Alley, Football Street
**City**
Arak
**Province**
Markazi
**Postal code**
3815899881
**Phone**
+98 86 3276 3858
**Email**
kiyangolmohamadi@gmail.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**
Arak University of Medical Sciences

**Full name of responsible person**
Alireza Rezaei Ashtiani

**Position**
specialist

**Latest degree**
Specialist

**Other areas of specialty/work**
Neurology

**Street address**
No.3345, Mir Ahmad Doctors Building,Adalat Alley, Shahid Beheshti St, Arak

**City**
Arak

**Province**
Markazi

**Postal code**
٣٨١٩٦٩٣٣٤٥

**Phone**
+98 86 3223 9388

**Email**
farahaniheidar@yahoo.com

## Person responsible for updating data

**Contact**

**Name of organization / entity**
Arak University of Medical Sciences

**Full name of responsible person**
Haidar Farahani

**Position**
Associate Professor

**Latest degree**
Ph.D.

**Other areas of specialty/work**
Biochemistry

**Street address**
Biochemistry section, Medical School, University Complex of the Great Prophet, Basij Square, Sardasht St, Arak

**City**
Arak

**Province**
Markazi

**Postal code**
3848176341

**Phone**
+98 86 3417 3520

**Email**
farahaniheidar@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**
Not applicable

**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**
Not applicable

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