Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)

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+98 86 3276 3822

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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
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2

Recruitment center
Name of recruitment center
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Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
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
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Full name of responsible person
Zahra Goodarzi
Position
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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