Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Nov 2026

Evaluation of safety and efficacy of oral curcuden on remitting and relapsing multiple sclerosis patients (RRMS): clinical trial study of Phase A2

Protocol summary

Study aim

The effect of Curcuden on RRMS patients will be investigated

Design

We randomly divide 68 MS patients into intervention and control groups and we assign a code to each participant.

Settings and conduct

This study conduct in the Neurology Research Center of Tehran Imam Khomeini Hospital in double-blind manner. None of the patients are aware that in which group, control or intervention, they are. The doctor also prescribes the medicine as code A and B and no information is available n them about being placebo or medicine. The main neurologist of the project is the only one that is aware of this classification.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: RRMS patients who receive first-line treatment drugs for one year but have at least one relapse or active lesion. Meanwhile, at least one month away from the last attack of the disease and the patient's corticosteroid therapy. Patients should be between 18 to 60 years of age with EDSS between 0 and 5.5, and no Curcumin contraindications. Exclusion criteria: Progressive MS patients or patients who have contraindication to use Curcumin or similar substances. The presence of any internal or systemic disease (such as anemia or liver conditions). Every patient is examined by MRI, general and inflammatory factors, once before and once after treatment

Intervention groups

The intervention group receive the medication for 6 months at a dose of 180 mg per day. The control group receive placebo for a period of 6 months at a dose of 180 mg.

Main outcome variables

The amount of active lesions in the brain and spinal cord and the inflammatory factors of the blood will be compared before and after the treatment between the two groups of test and control. In this way, the efficacy and non-toxicity of the drug will be investigated

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170128032241N2**
Registration date: **2018-02-16, 1396/11/27**
Registration timing: **registered_while_recruiting**

Last update: **2019-08-20, 1398/05/29**
Update count: **1**

Registration date

2018-02-16, 1396/11/27

Registrant information

Name

Maryam Mohajeri

Name of organization / entity

Alborz Nanomed Tech Co.

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Alborz Nanomed Tech Co. , Maryam Mohajeri

Expected recruitment start date

2017-10-23, 1396/08/01

Expected recruitment end date

2018-10-23, 1397/08/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of safety and efficacy of oral curcuden on remitting and relapsing multiple sclerosis patients (RRMS): clinical trial study of Phase A2

Public title
Effect of oral curcuden on multiple sclerosis patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
RRMS patients who will receive first-line treatment drugs for one year Have at least one relapse or active lesion At least one month has passed since the last attack of the disease At least one month ha passed from the patient's corticosteroids Average age of 18 to 60 years 0 <EDSS <5.5 No curcumin contraindications
Exclusion criteria:
Progressive MS patients Patients who have contraindicated curcumin or similar substances The presence of any internal or systemic illness (such as anemia or liver problems)
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data and Safety Monitoring Board

Sample size
Target sample size: **68**
Randomization (investigator's opinion)
Randomized
Randomization description
Use a random number table, we assign patients the code within the specified interval, then we classify the odd codes in the intervention group and the even codes in the control group.
Blinding (investigator's opinion)
Double blinded
Blinding description
We mark drug with code A and placebo with the code B, only the analyst is aware of this codes, each group of patients receive A or B randomly, the physician and the patient are not aware of this codes.
Placebo
Used
Assignment
Parallel
Other design features
Random Numbers Table

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid Beheshti Medical University
Street address
7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran.
City
Tehran
Province
Tehran
Postal code
1419733141
Approval date
2019-07-29, 1398/05/07
Ethics committee reference number
IR.SBMU.REC.1398.054

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(Multiple sclerosis)

Primary outcomes

1

Description
Active lesions in the brain and spinal cord (plaque)
Timepoint
Before the intervention (month 0) and the sixth month after the intervention
Method of measurement
MRI

2

Description
Blood inflammatory factors
Timepoint
Before the intervention (month 0) and the sixth month after the intervention
Method of measurement
Blood Test

Secondary outcomes

1

Description
Clinical relapse within 6 months
Timepoint
Every 6 months
Method of measurement
MRI

2

Description
Effect of medication on other MRI parameters such as T2 lesions, new T2 lesions and brain atrophy
Timepoint
Every 6 months
Method of measurement
MRI

3

Description
Effect of medication on changes in inflammatory and anti-inflammatory mediators
Timepoint
Before intervention and 6 months after intervention
Method of measurement
Blood test

4

Description
Effect of medication on improving patient lifestyle
Timepoint
Before intervention and 6 months after intervention
Method of measurement
EDSS Criteria, Fatigue, Focus, Balance ...

Intervention groups

1

Description
Intervention group 1: 34 RRMS patients who received at least 6 months of first line treatment of MS (beta-interferon) but have clinically experienced at least one relapse during medication or an active lesion in their brain or spinal cord.
Category
Treatment - Drugs

2

Description
Control group: 34 RRMS patients who receive at least 6 months of first line treatment of MS (beta-interferon) but have clinically experienc at least one relapse during medication or an active lesion in their brain or spinal cord.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam khomeini Iran Neurology Research Center
Full name of responsible person
Bahaadin Siroos
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Alborz Nanomed Tech Co.
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
Alborz Nanomed Tech Co.
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity
Alborz Nanomed Tech Co.

Full name of responsible person
Maryam Mohajeri

Position
CEO

Latest degree
Ph.D.

Other areas of specialty/work
Medical Genetics

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Associate Professor

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

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
No - There is not 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
Clinical study report In this report, the analysis of final information related to the main implications of the study will be published in scientific papers in international journals. No patient information or study has been published in this article.

When the data will become available and for how long
Start access from the date of publication of the study results

To whom data/document is available

This data will be applicable to anyone who has access to the full text of the scientific article, including researchers and other individuals.

Under which criteria data/document could be used

These documents can be used as research results and cited in other papers and scientific projects. Also, these results can be used to design future phases of clinical study. Certainly, in the case of the registration of intellectual property, the right to use this data in the industry is the sole owner of the project.

From where data/document is obtainable

These data will be available in the published articles of this project. Obviously, after publication of the articles, the referral address and the link with the author of the article will be available to the applicant in the available scientific journal to receive the documentation.

What processes are involved for a request to access data/document

The documentation will be available to anyone who has access to the full text of the article. If additional information is requested from the applicant, the author will be responsible for posting the article and requesting the data, if agreed upon by the author and the owner. The required information plan will be available to the applicant in less than 1 month.

Comments

No more information