Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Therapeutic effects of Curcumin in patients with amyotrophic lateral sclerosis reffered to neurologic research center of imam khomeini hospital

Protocol summary

Summary

In this double-blind randomized clinical trial, 60 patients with probable or definite ALS based on revised El Escorial criteria referred to Imam Khomeini hospital between March 2015 and 2016,will be studied. An age range of 18 to 85 years, time has passed since the onset of the symptoms till inclusion 2 years or less and mild to moderate disability based on ALSFRS-r is the inclusion criteria and familial ALS in first-degree relatives, pregnancy or breastfeeding and severe renal, liver or heart dysfunction are the major exclusion criteria. All participants will sign the informed consent prior to inclusion in the study. Patients will receive either 80 milligrams of Curcumin sina capsules (30 patients) or placebo (30 patients) besides Rilozule for 3 months. In order to avoid gastrointestinal side effects of Curcumin, anti-acids will be prescribed for the patients. Patients clinical status will be evaluated by compound muscle action potential (CMAP) in ulnar and proneal nerves and functional status of the patients will be evaluated by revised ALS Functional Rating Scale (ALSFRS-r), manual muscle testing (MMT) and amyotrophic lateral sclerosis assessment questionnaire (ALSAQ-40); medication side effects will be assessed during this 3 months.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015062411424N3**
Registration date: **2016-07-01, 1395/04/11**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-07-01, 1395/04/11

Registrant information

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Iranian Center of Neurological Research
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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2015-03-20, 1393/12/29

Expected recruitment end date

2016-03-19, 1394/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Therapeutic effects of Curcumin in patients with amyotrophic lateral sclerosis reffered to neurologic research center of imam khomeini hospital

Public title

Therapeutic effects of Curcumin capsule in patients with amyotrophic lateral sclerosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with an age range of 18 to 85;

Probable or definite ALS (based on revised El Escorial criteria); Time passed since onset of the symptoms till inclusion be 2 years or less; Mild to moderate disability (based on ALSFRS-r) Exclusion criteria: Familial ALS in first-degree relatives; Pregnancy or breastfeeding; Severe renal, liver or heart dysfunction; HIV positive patients; Prominant cognitive impairment

Age

From **18 years** old to **85 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Qods Street, Keshavarz blv.

City

Tehran

Postal code

Approval date

2016-05-30, 1395/03/10

Ethics committee reference number

IR.TUMS.REC.1395.2646

Health conditions studied

1

Description of health condition studied

Amyotrophic lateral sclerosis(AlS)

ICD-10 code

G12.2

ICD-10 code description

Motor neuron disease

Primary outcomes

1

Description

patients clinical function changes

Timepoint

baseline,3 months after intervention

Method of measurement

ALS Functional Rating Scale

Secondary outcomes

1

Description

compound muscle action potential (CMAP) changes in ulnar nerve

Timepoint

baseline, 3 months after intervention

Method of measurement

EMG-NCV

2

Description

muscle strength changes

Timepoint

baseline, 3 months after intervention

Method of measurement

Manual muscle testing

3

Description

compound muscle action potential (CMAP) changes in proneal nerve

Timepoint

baseline, 3 months after intervention

Method of measurement

EMG-NCV

4

Description

quality of life

Timepoint

baseline, 3 months after intervention

Method of measurement

ALSAQ-40

5

Description

medication side effects

Timepoint

3 months after intervention

Method of measurement

questionnaire

Intervention groups

1

Description
Control: In this group, patients will recieve capsule placebo daily besides tablet Riluzole 50mg BD
Category
Placebo

2

Description
Intervention: In this group, patients will recieve capsule Sina Curcumin 80 mg daily and tablet Riluzole 50mg BD
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital Complex
Full name of responsible person
Abbas Tafakhori
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Masood Yunesian
Street address
Tehran University of Medical Sciences, Qods Street, Keshavarz Blvd.
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
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Person responsible for updating data

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Fax

Email

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty