

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Therapeutic effects of Curcumin in patients with amyotrophic lateral sclerosis referred 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 Riluzole 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 pronator teres 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

##### Name

Abbas Tafakhori

##### Name of organization / entity

Iranian Center of Neurological Research

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6691 0491

##### Email address

a\_tafakhori@sina.tums.ac.ir

#### 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 referred 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 receive capsule placebo daily besides tablet Riluzole 50mg BD

#### Category

Placebo

### 2

#### Description

Intervention: In this group, patients will receive 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

##### Full name of responsible person

Abbas Tafakhori

##### Position

Neurologist

##### Other areas of specialty/work

##### Street address

Imam Khomeini hospital, End of Keshavarz Blvd.

##### City

Tehran

##### Postal code

##### Phone

+98 21 6119 2424

##### Fax

##### Email

abbas.tafakhori@gmail.com

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Abbas Tafakhori

##### Position

Neurologist

##### Other areas of specialty/work

##### Street address

Imam Khomeini hospital, End of Keshavarz Blvd.

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##### Email

abbas.tafakhori@gmail.com

##### Web page address

## Person responsible for updating data

#### Contact

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Elmira Agah

##### Position

##### Other areas of specialty/work

##### Street address

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

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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*