

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Sep 2026

### Evaluation of the effectiveness of Edaravone compared with placebo in maintaining muscle strength, functional status, and quality of life in patients with amyotrophic lateral sclerosis

#### Protocol summary

Muscle strength; Functional status; Quality of life

##### Study aim

In this study, investigators aimed to assess the treatment effect of Edaravone in patients with Amyotrophic Lateral Sclerosis (ALS) in a representative Iranian population

##### Design

This is a prospective, phase 2/3, parallel group, Randomized clinical trial. In this study patients, will be randomly distributed in to two groups (case & control). Each group will contain about 10 participants.

##### Settings and conduct

This study will conduct in Alzahra hospital of Esfahan. Patients will be visited at the time of enrollment and 3, 6, 9, and 12 months later. In each visit, the doctor will interview with the patients and examine their muscular strength and neural system.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients diagnosed as definite or probable ALS disease according to El Escorial Criteria; ALS patients who are graded as mild or moderate according to ALS Health State Scale; the patient gets at least 2 points on all 12 items of the ALSFRS-R; Forced vital capacity of at least 80% in spirometry; Desire of the patient to participate in this study and Signing Written Informed Consent  
Non-Inclusion criteria: Patients diagnosed as possible ALS disease according to El Escorial Criteria; ALS patients who are graded as severe or terminal according to ALS Health State Scale; the patient can't get at least 2 points on all 12 items of the ALSFRS-R; the patient administers another drug or herb for ALS treatment; Unwillingness of patient to enter the clinical trial

##### Intervention groups

There will be 2 groups. In the case group, patients will receive Riluzole and Edaravone. In the control group, patients will receive Riluzole and placebo.

##### Main outcome variables

#### General information

##### Reason for update

##### Acronym

Isfahan ALS Registry

##### IRCT registration information

IRCT registration number: **IRCT20190324043105N1**

Registration date: **2019-04-26, 1398/02/06**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-04-26, 1398/02/06**

Update count: **0**

##### Registration date

2019-04-26, 1398/02/06

##### Registrant information

##### Name

Alireza Eishi Oskouei

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3668 3554

##### Email address

alireza.eishi@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-03-16, 1395/12/26

##### Expected recruitment end date

2019-03-16, 1397/12/25

##### Actual recruitment start date

2017-03-16, 1395/12/26

##### Actual recruitment end date

2019-06-16, 1398/03/26  
**Trial completion date**  
 2019-09-16, 1398/06/25

**Scientific title**  
 Evaluation of the effectiveness of Edaravone compared with placebo in maintaining muscle strength, functional status, and quality of life in patients with amyotrophic lateral sclerosis

**Public title**  
 Effect of Edaravone in treatment of ALS

**Purpose**  
 Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
 Patients diagnosed as definite or probable ALS disease according to El Escorial Criteria ALS patients who are graded as mild or moderate according to ALS Health State Scale. The patient gets at least 2 points on all 12 items of the ALSFRS-R. Forced vital capacity of at least 80% in spirometry. Desire of the patient to participate in this study and Signing Written Informed Consent.  
**Exclusion criteria:**  
 Patients diagnosed as possible ALS disease according to El Escorial Criteria ALS patients who are graded as severe or terminal according to ALS Health State Scale. The patient can't get at least 2 points on all 12 items of the ALSFRS-R. The patient administers another drug or herb for ALS treatment. Unwillingness of patient to enter the clinical trial

**Age**  
 From **18 years** old to **75 years** old

**Gender**  
 Both

**Phase**  
 2-3

**Groups that have been masked**  
*No information*

**Sample size**  
 Target sample size: **20**  
 Actual sample size reached: **23**

**Randomization (investigator's opinion)**  
 Randomized

**Randomization description**  
 Patients entering the study will be divided into two groups of case and control by simple randomization technique (using statistical software). The unit of randomization will be "individual". After patients entered the study, each one will be numbered from 1 to 20. Then, "random number generator" software, will generate 10 random numbers from 1 to 20. Patients with equal numbers to random numbers will enter to the case group, and the other patients will enter to the control group.

**Blinding (investigator's opinion)**  
 Not blinded

**Blinding description**

**Placebo**  
 Used

**Assignment**  
 Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethical Committee of Isfahan University of Medical Sciences

##### Street address

Isfahan University of Medical Sciences, Hezar Jarib Ave., Isfahan, Iran

##### City

Isfahan

##### Province

Isfahan

##### Postal code

81746 73461

#### Approval date

2017-05-26, 1396/03/05

#### Ethics committee reference number

IR.MUI.REC.1396.3.569

## Health conditions studied

### 1

#### Description of health condition studied

Amyotrophic Lateral Sclerosis

#### ICD-10 code

G12.21

#### ICD-10 code description

Progressive muscular atrophy; Restrictive lung disease due to amyotrophic lateral sclerosis; Restrictive lung mechanics due to als

## Primary outcomes

### 1

#### Description

Functional evaluation of patient's muscle strength

#### Timepoint

At the time of enrolling the patient to study, and then every 3 moths in the following period of 1 year

#### Method of measurement

Manual Muscle Testing (MMT)

### 2

#### Description

Functional status of the patient

#### Timepoint

At the time of enrolling the patient to study, and then every 3 moths in the following period of 1 year

#### Method of measurement

Amyotrophic Lateral Sclerosis Functional Rating Scale-

### 3

#### **Description**

Quality of life in the patients

#### **Timepoint**

At the time of enrolling the patient to study, and then every 3 months in the following period of 1 year

#### **Method of measurement**

Amyotrophic Lateral Sclerosis Assessment Questionnaire (ALSAQ-40)

### **Secondary outcomes**

empty

### **Intervention groups**

#### 1

#### **Description**

Intervention group: Riluzole + Edaravone; In this group, patients treated with Iranian Riluzole (Rilumax 50 mg tablet, tehrandarou Pharma Corporation) and Edaravone (60 mg Radicut vial, Mitsubishi Tanabe Pharma Corporation, Japan). During the study period, patients will administer 50 mg Riluzole tablet every 12 hours orally. 60 mg Edaravone vial will be diluted in 100 ml of normal saline and then patients will administer Edaravone via slow intravenous infusion. Edaravone will be prescribed in 4-week cycles. In the first cycle, patients will only inject the drug within the first 14 days. In the next 11 cycles, patients will only inject the drug within the first 10 days.

#### **Category**

Treatment - Drugs

#### 2

#### **Description**

Control group: Riluzole + Placebo (normal saline); In this group, patients treated with Iranian Riluzole (Rilumax 50 mg tablet, tehrandarou Pharma Corporation) and Placebo (normal saline). During the study period, patients will administer 50 mg Riluzole tablet every 12 hours orally. as the placebo 100 ml of normal saline via slow intravenous infusion will be injected. normal saline will be injected in 4-week cycles. In the first cycle, patients will only inject the placebo within the first 14 days. In the next 11 cycles, patients will only inject the placebo within the first 10 days.

#### **Category**

Treatment - Drugs

### **Recruitment centers**

#### 1

#### **Recruitment center**

**Name of recruitment center**  
Alzahra University Hospital

#### **Full name of responsible person**

Alireza Eishi Oskoue

#### **Street address**

EMG Department, Alzahra University Hospital, Soffeh Blvd., Isfahan

#### **City**

Isfahan

#### **Province**

Isfahan

#### **Postal code**

8174675731

#### **Phone**

+98 31 3620 2020

#### **Email**

alireza.eishi@yahoo.com

### **Sponsors / Funding sources**

#### 1

#### **Sponsor**

#### **Name of organization / entity**

Esfahan University of Medical Sciences

#### **Full name of responsible person**

Dr Shaghayegh Haghjoo

#### **Street address**

Isfahan University of Medical Science, Hezar Jarib Street, Isfahan

#### **City**

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#### **Province**

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#### **Postal code**

8174675731

#### **Phone**

+98 31 3620 2020

#### **Email**

basiri.keivan@gmail.com

#### **Grant name**

#### **Grant code / Reference number**

#### **Is the source of funding the same sponsor organization/entity?**

Yes

#### **Title of funding source**

Esfahan 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**

Esfahan University of Medical Sciences

**Full name of responsible person**

Alireza Eishi Oskouei

**Position**

Medical Intern

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Neuroscience

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Keivan Basiri

**Position**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Neurology

**Street address**

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**Phone**

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**Email**

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**Person responsible for updating data****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

after finishing this trial, MMT, ALSFRS-R, and ALSAQ-40 scores of all patients will be shared with all researchers .

**When the data will become available and for how long**

starting 6 months after publication

**To whom data/document is available**

people working in academic institutions

**Under which criteria data/document could be used**

the deidentified individual participant data will be available only for research purposes.

**From where data/document is obtainable**

alireza.eishi@yahoo.com

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

by sending his/her request to mentioned Email, within less than a month: alireza.eishi@yahoo.com

**Comments**