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

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 recieve Riluzole and Edaravone. In the control group, patients will recieve Riluzole and placebo.

Main outcome variables
Muscle strength; Functional status; Quality of life

General information

Reason for update

Acronym
Isfahan ALS Registery

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

Isfehan

Province

Isfehan

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-

Revised (ALSFRS-R)

3

Description
Quality of life in the patients
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 Assessment Questionnaire (ALSAQ-40)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Riluzule + Edaravone; In this group, patients treated with Iranian Riluzule (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 Riluzule 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: Riluzule + Placebo (normal saline); In this group, patients treated with Iranian Riluzule (Rilumax 50 mg tablet, tehrandarou Pharma Corporation) and Placebo (normal saline). During the study period, patients will administer 50 mg Riluzule 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 Oskouei
Street address
EMG Department, Alzahra University Hospital, Soffeh Blvd., Isfehan
City
Isfehan
Province
Isfehan
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, Isfehan
City
Isfehan
Province
Isfehan
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
Street address
EMG Department, Alzahra University Hospital, Soffeh Blvd., Isfehan
City
Isfehan
Province
Isfehan
Postal code
8174675731
Phone
+98 31 3620 2020
Email
alireza.eishi@yahoo.com

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
EMG Department, Alzahra University Hospital, Soffeh Blvd., Isfehan
City
Isfehan
Province
Isfehan
Postal code
8174675731
Phone
+98 31 3620 2020
Email
basiri.keivan@gmail.com

Person responsible for updating data

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
Street address
EMG Department, Alzahra University Hospital, Soffeh Blvd., Isfehan
City
Isfehan
Province
Isfehan
Postal code
8174675731
Phone
+98 31 3620 2020
Email
alireza.eishi@yahoo.com

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