Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Oct 2026

Evaluating the effect of bometanide on spasticity in patients with ALS

Protocol summary

Study aim
Evaluating the modulatory effect of bometanide on increased irritability and associated neurophysiological symptoms in ALS patients.

Design
Patients are randomly assigned in a 1:1 ratio to groups of bumetanide or placebo by use of a block randomisation scheme. With the 95 % confidence level, power set at 80%, and a potential attrition rate of 10%, the sample size required to detect differences is 11 for each group

Settings and conduct
This interventional and therapeutic study is performed on patients with ALS in Firoozgar Hospital. Patients in the bumetanide group will take 2 mg of bometanide twice daily for 3 month, and patients in the placebo group will receive a placebo in the same way, and its effects will be evaluated through MUNIX and ALSFRS-R tests. All stages of the trial and patient information and the results will be blind to physicians, researchers, patients and the information analysis team until the end of the statistical analysis.

Participants/Inclusion and exclusion criteria
Inclusion criteria: aged 18 to 80 years. able to swallow tablets/capsules. slow vital capacity (SVC) greater than or equal to 50% Exclusion criteria: having kidney or liver dysfunction. history of laryngeal spasm. dystonia. and akathisia. history of neurological disease

Intervention groups
In the bumetanide group, 2 mg of bumetanide was administered twice daily for 3 months, and patients in the placebo group received placebo in the same way. All patients were visited weekly to monitor their symptoms, neurological and physical function.

Main outcome variables
Decrease in muscle spasticity of patients and increase ALSFRS-R test score

General information

Reason for update

Acronym
ALS

IRCT registration information
IRCT registration number: **IRCT20201020049089N1**
Registration date: **2020-12-15, 1399/09/25**
Registration timing: **prospective**

Last update: **2020-12-15, 1399/09/25**
Update count: **0**

Registration date
2020-12-15, 1399/09/25

Registrant information

Name
Mohsen Sedighi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 8862 2578

Email address
sedighi.mo@iums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-12-21, 1399/10/01

Expected recruitment end date
2021-02-19, 1399/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluating the effect of bometanide on spasticity in patients with ALS

Public title

Evaluating the effect of bumetanide on ALS

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

1. No history of other neurological diseases such as stroke and dementia 2. No orthopedic problems 3. Not having diabetes. addiction. hepatitis 4. The patient's education level at least up to the fifth grade

Exclusion criteria:

1. Lack of cooperation of the patient during testing and exercises 2. Failure to refer the patient for the second stage tests after the interventions 3. Patients whose diet is changed.

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

2-3

Groups that have been masked

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

Sample size

Target sample size: **25**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, ALS patients referred to the medical center were randomly divided into two groups of bometanid and placebo using a randomized block design with two blind strains in a ratio of 1: 1. All the identity and medical information of the participants in the two groups will be covered on all the researchers until the end of the study and statistical analysis of the study results.

Blinding (investigator's opinion)

Double blinded

Blinding description

All participants and their caregivers, clinicians, researcher and data analysts will be blinded to treatment assignments until final data analysis.

Placebo

Used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Hemmat highway

City

Tehran

Province

Tehran

Postal code

14665354

Approval date

2020-11-22, 1399/09/02

Ethics committee reference number

IR.IUMS.REC.1399.904

Health conditions studied

1

Description of health condition studied

Amyotrophic lateral sclerosis

ICD-10 code

G12.21

ICD-10 code description

Amyotrophic lateral sclerosis

Primary outcomes

1

Description

MUNIX and ALSFRS-R

Timepoint

Before and after intervention

Method of measurement

ALSFRS-R questionnaire and electromyogram device

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group, ALS patients will be treated with bometanid at a dose of 2 mg every 12 hours as an oral tablet for 3 months.

Category

Treatment - Drugs

2

Description

Control group: In this group, ALS patients will be treated with placebo for 3 months, which is completely similar to bometanide in terms of appearance such as shape and color and will be taken orally every 12 hours.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Firoozgar hospital

Full name of responsible person
Dr. Bahram Haghi

Street address
Valiasr Square, Karim Khan St., Beh Afarin St., Firoozg Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences

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
Iran 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
Iran University of Medical Sciences

Full name of responsible person
Mohammad Taghi Jogharaei

Position
Professor

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Neuroscience

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All information about the results of the drug intervention on the participants can be shared after making individuals unidentified.
When the data will become available and for how long
1 year after the publication of the article
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
Conditions for access to study data is to use in clinical and research studies in affiliated centers.
From where data/document is obtainable
Faculty of Advance Technologies in Medicine. Department of Neuroscience. Dr. Mohammad Taghi Joghtaei (Department Manager)
What processes are involved for a request to access data/document
Access to the data requires approval from the Vice President for Research and the Ethics Committee.
Comments