Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jul 2026

Effect of Riluzole on cognitive function of patients with mild Alzheimers disease: a double-blind randomized clinical trial, placebo-controlled

Protocol summary

Study aim

Study of the effect of Riluzole on the cognitive function of patients with mild Alzheimer's disease

Design

This study is a randomized clinical trial trial, placebo-controlled, double-blind that will be conducted between 2018 -2019. study population is the patient with mild Alzheimer's disease, aged 60-80 years old. A total of 48 patients are randomly divided into two equal groups of placebo and main drug group. Randomization will be done by using the four block size.

Settings and conduct

Patients referred to Shariati Hospital's neurology clinic and private neurology clinic who are eligible for study are randomly divided into two groups of main drug and placebo. The intervention group received 50 mg oral Riluzole tablets twice a day for three months and the placebo group received in the same way . Patients will be evaluated in terms of disease progression, cognitive function, and memory performance on day one and 90th of study . They are also considered for drug side effects during the study. Patients and the main investigators who measure the outcomes will be blinded to The type of medication .

Participants/Inclusion and exclusion criteria

Patients with mild Alzheimer's disease aged 60-80 years old who received one of the FDA approved anticholinesterase drugs for Alzheimer's treatment from three months ago, will be included in the study, and patients with a history of other types of dementia and other neurological diseases and major psychiatric disorders, and history of hypertension and Uncontrolled diabetes will not be included in the study

Intervention groups

Intervention includes the administration of oral tablets of Riluzole in intervention group and the administration of placebo tablets in the control group.

Main outcome variables

Evaluation of cognitive function; memory performance and progression of Alzheimer's disease are the main outcomes of the study

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100126003181N4**
Registration date: **2018-03-01, 1396/12/10**
Registration timing: **prospective**

Last update: **2018-03-01, 1396/12/10**
Update count: **0**

Registration date

2018-03-01, 1396/12/10

Registrant information

Name

Zahra Mokhtari

Name of organization / entity

Otorhinolaryngology research center, Tehran university of medical sciences

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-21, 1397/02/01

Expected recruitment end date

2019-10-23, 1398/08/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of Riluzole on cognitive function of patients with mild Alzheimers disease: a double-blind randomized clinical trial, placebo-controlled

Public title
Effect of Riluzole on Alzheimer's Disease
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Having of mild type of Alzheimer's Disease Receiving one of the anticholinesterase drugs for treating Alzheimer's from three months ago aged between 60-80
Exclusion criteria:
Having any other type of Dementia Any history of using Memantine or Riluzole History of using medications with glutamatergic interaction History of alcohol and opium abuse History of diseases such as Parkinson's disease, epilepsy, stroke, high blood pressure, uncontrolled diabetes, MS, mental retardation, CNS tumors, Huntington, subdural Hematoma, history of major psychiatric diseases History of severe head trauma that results in loss of consciousness
Age
From **60 years** old to **80 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **48**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization will be done by 4 block size.
Blinding (investigator's opinion)
Double blinded
Blinding description
Since the placebo is exactly the same as the original medicine, and when informed consent is informed, the patient is randomly assigned to one of the drug or placebo groups, so the patient is not aware of the type of medication. Also, the main investigator who examined the initial outcome will be blind to patient's drug type, because the allocation is done by Secretary of the clinic.
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
Vice Chancellor for research, Tehran University of Medical Sciences, Ghods St, Keshavarz Blvd
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Tehran
Postal code
1417653761
Approval date
2018-02-03, 1396/11/14
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1396.4403

Health conditions studied

1

Description of health condition studied
Alzheimer Disease
ICD-10 code
G30
ICD-10 code description
Alzheimer's disease

Primary outcomes

1

Description
Cognitive function assessment
Timepoint
The first day and the 90th day of study
Method of measurement
Using the test of Mini Mental State Examination (MMSE)

2

Description
Assessment of memory
Timepoint
The first day and the 90th day of study
Method of measurement
Using the test of Delayed recall test

3

Description
Assessment of disease progression
Timepoint

The first day and the 90th day of study

Method of measurement

Using the Functional Assessment Staging Tool (FAST)

Secondary outcomes

1

Description

Drug side effect

Timepoint

fourth week

Method of measurement

ask from patient

Intervention groups

1

Description

Intervention group: Riluzole 50 mg oral tablet twice daily for three months

Category

Treatment - Drugs

2

Description

Control group: Placebo (similar to the original drug) oral twice daily for three months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati hospital

Full name of responsible person

Dr. Farzad Fatehi

Street address

North Kargar Ave.Shariati hospital

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2

Recruitment center

Name of recruitment center

private Clinic of Neurology

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Dr.Zahra Mokhtari

Position

PhD of Medical Physiology

Latest degree
Ph.D.
Other areas of specialty/work
Physiology
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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable