

# 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, 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

Iran (Islamic Republic of)

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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

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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

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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**

Dr. Maryam Norozian

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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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**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