

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

Evaluation of the effect of rivastigmine on decision making in mild cognitive impairment (MCI) patients by Cambridge Neuropsychological Test Automated Battery (CANTAB)

Protocol summary

Study aim

The effect of rivastigmine on decision-making power of mild cognitive impairment patients

Design

This study is phase III, randomized, two armed, parallel, double blinded (volunteers and analysis team), active controlled, which is performed in 40 patients with mild cognitive impairment in Roozbeh Hospital.

Settings and conduct

This study is performed on patients with cognitive impairment referred to Roozbeh Hospital. Patients randomly receive rivastigmine or placebo twice daily for 3 months. The specific code of each patient is written on the research label of each pill package, which is opaque. If needed, the dose is increased by 1.5 mg every two weeks. Due to the similarity of the placebo and drug packages and also random codes which are used to identify them, the patients will not be informed about the type of drug they received. Also according to the identity codes of each patient the study data will be provided anonymously to the study results analysis team. Thus, the study is blinded for the patient and the evaluator.

Participants/Inclusion and exclusion criteria

Patients with mild cognitive impairment, which are diagnosed based on the Fast = 3 criterion, enter the study after obtaining informed consent. In case of major neurological disorder, history of seizures and bradycardia patients will not be able to enter the study.

Intervention groups

Patients with mild cognitive impairment are randomly divided into two groups of drugs and placebo in two groups of 20 people. In the intervention group, patients treated with rivastigmine initially receive 1.5 mg capsules twice daily, which can be increased to 3 mg twice daily after 2 weeks, depending on the possible side effects and response to treatment. Increasing the dose of the drug is also applied in placebo.

Main outcome variables

Effect on decision making

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201104049257N1**

Registration date: **2021-05-10, 1400/02/20**

Registration timing: **registered_while_recruiting**

Last update: **2021-05-10, 1400/02/20**

Update count: **0**

Registration date

2021-05-10, 1400/02/20

Registrant information

Name

Setayesh Sadeghi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-21, 1400/02/01

Expected recruitment end date

2021-11-22, 1400/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of the effect of rivastigmine on decision making in mild cognitive impairment (MCI) patients by Cambridge Neuropsychological Test Automated Battery (CANTAB)

Public title
Rivastigmine effect on mild cognitive impairment patients decision making

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Mild cognitive impairment diagnosis on Functional Assessment Staging Test (FAST)=3 Age more than 40 Third grade education Mini-mental state examination between 24 to 30
Exclusion criteria:
Psychiatric disorder history Untreated depression Vitamin b12 deficiency Uncontrol hypothyroidism Drug abuse during 6 month ago Seizure history Major neurologic disorder Stroke Cholinesterase inhibitor administration during 6 month ago Other disease interfere with decision making Heart block, bradycardia (heart rate<60) Gastrointestinal bleeding during 6 month ago Pregnancy and lactation Rivastigmine allergy

Age
From **40 years** old

Gender
Both

Phase
3

Groups that have been masked

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

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Patient randomization is done online (sealedenvelope.com). Using 4 blocks (Permuted balance Block) for a total of 72 patients with a 1: 1 allocation ratio, this random chain and anonymous codes consisting of 2 letters and a number will be made. When random assignment is made, four letters (corresponding to the first two letters of the first name and the first two letters of the last name) are added to these codes. On the package of drugs, the research label and the relevant codes are already inserted according to the produced sequence.

Blinding (investigator's opinion)
Double blinded

Blinding description

This study is designed to be double-blind. Research labeling will be done on two products. All the drugs used in the study are in completely opaque packages and their lids will be packaged with a disposable label. This package contains the corresponding randomization code. In this way, patients and physicians evaluating the clinical outcome will not be aware of the allocation of patients in treatment groups. Finally, all data will be coded for analysis.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Institute of Pharmaceutical Sciences-Tehran
University of Medical Sciences

Street address

Poursina Avenue, Tehran University of Medical Sciences, Faculty of Pharmacy, The Institute of Pharmaceutical Sciences (TIPS), PO Box. 14176-13151, Iran

City

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Approval date

2021-03-09, 1399/12/19

Ethics committee reference number

IR.TUMS.TIPS.REC.1400.010

Health conditions studied

1

Description of health condition studied

Mild Cognitive Impairment (MCI)

ICD-10 code

G31.84

ICD-10 code description

Mild cognitive impairment, so stated

Primary outcomes

1

Description

Effect on decision making

Timepoint

3 months from the start of the intervention

Method of measurement

CANTAB test including CGT (Gambling Cambridge Test)
.IST (Information Task Sampling) , SST (Stop Signal Task)

Secondary outcomes

1

Description

Adverse event evaluation

Timepoint

Every two weeks

Method of measurement

Ask questions of the patient and record information

Intervention groups

1

Description

Intervention group: Pack of 30 oral capsules of rivastigmine (hydrogen titrate) 3 mg Hakim Pharmaceutical Company twice a day

Category

Treatment - Drugs

2

Description

Control group: Pack of 30 oral capsules of rivastigmine (hydrogen titrate) 3 mg Hakim Pharmaceutical Company twice a day

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Roozbeh Psychiatry Hospital

Full name of responsible person

Setayesh Sadeghi

Street address

South Kargar Street, below the Lashgar intersection

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<http://roozbehhospital.tums.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohamad Ali Sahraiyani

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Keshavarz Boulevard, corner of Quds Street, Central University Organization, sixth floor, Vice Chancellor for Research and Technology

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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

Setayesh Sadeghi

Position

Pharmacotherapy candidate

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
due to confidentiality
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available