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)
Phone
+98 21 8835 1384
Email address
sadeghis@razi.tums.ac.ir

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

Tehran

Province

Tehran

Postal code

14176-13151

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
City
Tehran
Province
Tehran
Postal code
13337159140
Phone
+98 21 5541 9151
Email
hosp_roozbeh@tums.ac.ir
Web page address
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 Sahraiyan
Street address
Keshavarz Boulevard, corner of Quds Street, Central University Organization, sixth floor, Vice Chancellor for Research and Technology
City
Tehran
Province
Tehran
Postal code
1417653911
Phone
+98 21 8163 3698
Email
vcr@tums.ac.ir
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
Street address
No. 51, Unit 7, 4th Floor, 21st West Alley, Islamic Revolution Veterans Boulevard, North Amirabad
City
Tehran
Province
Tehran

Postal code
1437654359
Phone
+98 21 8835 1384
Email
sadeghi.setayesh@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Niayesh Mohebi
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Medical Pharmacy
Street address
South Kargar Street, below the Lashgar intersection
City
Tehran
Province
Tehran
Postal code
13337159140
Phone
+98 21 5541 9151
Email
niayesh_mohebbi@yahoo.com

Person responsible for updating data

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
Street address
No. 51, Unit 7, 4th Floor, 21st West Alley, Islamic Revolution Veterans Boulevard, North Amirabad
City
Tehran
Province
Tehran
Postal code
1437654359
Phone
+98 21 8835 1384
Email
sadeghi.setayesh@gmail.com

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