Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the effect of Donepezil Hydrochloride on memory impairment in patients recovered from Covid-19 with hospitalization history in comparison with the control group

Protocol summary

Study aim

Evaluation of the effect of Donepezil Hydrochloride on memory impairment in patients recovered from Covid19 with a history of hospitalization; Evaluation of memory impairment before and after drug administration in the case group (drug recipient); Evaluation of memory impairment in the control group simultaneously with the case group; Comparison of case group with control group in terms of improvement of memory impairment before, one, three and six months after drug administration

Design

Randomized single blind clinical trial with control group with parallel groups, phase 3 on at least 70 patient using a table of random numbers in Excel

Settings and conduct

This study is performed on Covid19 recovered patients with a history of hospitalization about one month ago who have referred to the Family Hospital`s clinic and have memory impairment. This study is single blinded (the data analyzer (statistic counselor) is blind).

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients between 20-50 years old that recovered from Covid-19, with a history of hospitalization ; suffer from memory impairment after recovery from Covid19 Exclusion criteria: History of previous cognitive problems, stroke, head trauma or cerebral hemorrhage, physical and psychiatric disease; Use of drugs with effect on cognitive function ;Consumption of drugs, stimulants and alcohol

Intervention groups

Covid19 recovered patients with a history of hospitalization about a month ago who have memory impairment are randomly divided into case group (receiving Donepezil) and control group and they are evaluated about memory indexes before, one month, three month and six month after intervention.

Main outcome variables

Evaluation and comparison of Wechsler memory scale scores in case and control groups before drug administration, one month later, three months later and six months after drug administration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210816052203N1**
Registration date: **2021-08-24, 1400/06/02**
Registration timing: **prospective**

Last update: **2021-08-24, 1400/06/02**
Update count: **0**

Registration date

2021-08-24, 1400/06/02

Registrant information

Name

Parham Pooladgar

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-01, 1400/06/10

Expected recruitment end date

2022-04-09, 1401/01/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of Donepezil Hydrochloride on memory impairment in patients recovered from Covid-19 with hospitalization history in comparison with the control group

Public title

The effect of Donepezil on memory impairment after Covid-19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with the age between 20- 50 years old Memory impairment after recovery from Covid-19 Volunteer to participate in the study

Exclusion criteria:

History of previous cognitive problems History of CVA, head trauma or Cerebral hemorrhage History of underlying physical illnesses affecting cognitive function such as cancer, thyroid disorders, physical disorders with features of cognitive impairment such as Alzheimer's or any type of degenerative neurological disorder such as Parkinson's History of underlying mental illnesses such as major depression, anxiety disorders and psychotic disorders Use of drugs that affect cognitive function such as antidepressants, benzodiazepines, and anticonvulsants such as phenobarbital Drug, stimulant and alcohol using

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

- Data analyser

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are randomly divided into case groups (drug recipient) and control group with simple random method by using the random number table. The random number function was used to randomize and assign individuals to groups; Randomization using Excel software is as follows: First, in a column, the groups are entered as A, B and below each other; because the number of samples in each group is set to 35 (taking into account the sample loss), 35 A and 35 B must be entered in order and below each other. In the opposite column, random numbers are generated using the RAND command. In the next step, with using the sort command, random numbers are generated from small to large or vice versa, which causes the order of the groups A and B to be changed. In fact, using the new order, individuals are randomly assigned to the case and control groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

This study is a single blind that data analyzer, who is a consultant professor in statistics, meantime she is aware of the general objectives of the research, she is kept blind, in such a way that meantime each participant is assigned a code and participants are informed about the study process and how to assign groups, are classified randomly with using the table of random numbers in the case and control groups. The statistics counselor is informed about the objectives and general process of the research, but in order to prevent her possible bias in analyzing the data, the code of the control group and the case group is not mentioned and she is informed at the end of the study.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of AJA University of Medical Sciences

Street address

AJA University of Medical Sciences, Etemadzadeh Avenue, West Fatemi Street, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1411718541

Approval date

2021-08-15, 1400/05/24

Ethics committee reference number

IR.AJAUMS.REC.1400.125

Health conditions studied

1

Description of health condition studied

Memory impairment due to Post acute COVID-19 syndrome (LONG-Covid Syndrome)

ICD-10 code

B97.21

ICD-10 code description

SARS-associated coronavirus as the cause of diseases

classified elsewhere

Primary outcomes

1

Description
Score of Wechsler Memory Scale Test
Timepoint
Measurement of memory indices at the beginning of the study (before intervention), one month later, three months later and six months after the intervention
Method of measurement
The Wechsler Memory Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: This group is treated with Donepezil Hydrochloride with the brand name Aricept at a dose of 5 mg (half a tablet for the first 5 nights and then one tablet overnight for 3 months and from 3 months to 6 months after starting the drug are reached the dose10 mg daily). This drug is FDA-APPROVED for the treatment of Alzheimer's disease and is currently routinely prescribed in Iran.
Category
Treatment - Drugs

2

Description
Control group: This group is not face to special intervention and is examined in parallel with the case group in terms of memory indexes.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Khanevadeh Hospital (AJA)
Full name of responsible person
Mehdi Sakhabaksh
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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
Artesh 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
Artesh University of Medical Sciences
Full name of responsible person
Mehdi Sakhabakhsh
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Assistant professor
Latest degree
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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
Yes - There is a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Not applicable
Title and more details about the data/document
The clinical study report, study protocol and results will be published in the journal for the use of other researchers while maintaining the confidentiality of participants' individual information with their consent.
When the data will become available and for how long
6 month after publish of a journal
To whom data/document is available
All medical professionals and scientists
Under which criteria data/document could be used
If people need more information, they can ask the project supervisor.
From where data/document is obtainable
Dr. Mehdi Sakhabakhsh - AJA University of Medical Sciences drsakha2013@gmail.com
What processes are involved for a request to access data/document
If people need more information, they can ask the project supervisor
Comments