

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Comparing the effectiveness of Memoral herbaceous medicine and placebo in improving cognitive functions in Alzheimer patients

Protocol summary

Study aim

Determination of the effectiveness of Memoral herbaceous medicine on improvement of cognitive functions in patients with Alzheimer

Design

Clinical trial with parallel group design of 90 patients, two arm, blinded, randomization using simple randomization, phase 3

Settings and conduct

patients who visit emam Reza hospital and by the lab and imaging method confirmed alzheimer disease , be investigated.then patients randomly divide in 2 groups by simple randomization method.in such a way that the patients coded by even and odd number according to time of referral and patients whose code is even or odd are placed in the intervention or control group one by one without the knowledge of the person delivering the medicine and the patient herself..the executor put medicine in the closed envelope which the code and the patient's name are written on it. Then give them to medicine delivery. The delivery don't informed about envelope's content and patient also don't informed about medicine's name.this study is double blinded so patients and executor were keep blinded .

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients who alzheimer disease confirmed by imaging and lab results. Non-inclusion criteria: Patients suffering from other disease such as other dementia which imitate alzheimer disease; patients with contraindications to the drug such as pregnancy; patients who have taken other drugs to control alzheimer disease.

Intervention groups

Intervention group receive Memoral capsule (GOLDARU company product) BD with Donepezil 5 mg tablet BD. Control group receive placebo capsule BD with Donepezil 5 mg tablet BD for 3 months.

Main outcome variables

Cognitive functions based on Addenbrooke examination

questionnaire

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200204046367N1**

Registration date: **2020-04-21, 1399/02/02**

Registration timing: **registered_while_recruiting**

Last update: **2020-04-21, 1399/02/02**

Update count: **0**

Registration date

2020-04-21, 1399/02/02

Registrant information

Name

sadaf qafari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 3724 4137

Email address

s1d9fgh9f4ry@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-20, 1399/02/01

Expected recruitment end date

2020-07-22, 1399/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effectiveness of Memoral herbaceous medicine and placebo in improving cognitive functions in Alzheimer patients

Public title

The effect of Memorial in Alzheimer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Confirmation of Alzheimer's disease according to imaging and laboratory results

Exclusion criteria:

Patients suffering from other disease such as other dementia which imitate alzheimer disease patients with contraindications to the drug such as pregnancy patients who have taken other drugs to control alzheimer disease

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients randomly divided in two groups by simple randomization method.in such a way that the patients coded by even and odd number according to time of referral and patients whose code is even or odd are placed in the intervention or control group one by one without the knowledge of the person delivering the medicine and the patient herself.

Blinding (investigator's opinion)

Double blinded

Blinding description

The executor put medicine in the closed envelope which the code and the patient's name are written on it. Then give them to medicine delivery. The delivery don't informed about envelope's content and patient also don't informed about medicine's name.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

Street address

No 26, 120 alley; Daraii treet

City

Kermanshah

Province

Kermanshah

Postal code

6718833134

Approval date

2020-03-03, 1398/12/13

Ethics committee reference number

IR.KUMS.REC.1398.1189

Health conditions studied

1

Description of health condition studied

Alzheimer

ICD-10 code

G30

ICD-10 code description

Alzheimer's disease

Primary outcomes

1

Description

Cognitive function scores based on Addenbrooke's Cognitive Examination questionnaire

Timepoint

At the beginning of the study and 3 months after beginning of Memoral usage

Method of measurement

Addenbrooke's Cognitive Examination questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Memoral capsule (GOLDARU company product) BD with Donepezil 5 mg tablet BD for 3 months

Category

Treatment - Drugs

2

Description

Control group: placebo capsule BD with Donepezil 5 mg tab BD for 3 months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza hospital

Full name of responsible person

Sadaf Qafari

Street address

Zakariya Razi boulevard

City

Kermanshah

Province

Kermanshah

Postal code

6742775333

Phone

+98 83 3427 6300

Email

irhk@kums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Farid Najafi

Street address

Department number 2, Shahid Behshti boulevard

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Phone

+98 83 3838 4185

Email

farid_n32@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Sadaf Qafari

Position

Intern

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

Street address

No.26; 120 alley; Daraii street; Ferdowsi square

City

Kermanshah

Province

Kermanshah

Postal code

6718833134

Phone

+98 83 3724 4137

Fax

Email

s1d9fgh9f4ry@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Sadaf Qafari

Position

Intern

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

Street address

No.26; 120 alley; Daraii street; Ferdowsi square

City

Kermanshah

Province

Kermanshah

Postal code

6718833134

Phone

+98 83 3724 4137

Fax

Email

s1d9fgh9f4ry@gmail.com

Person responsible for updating data

s1d9fgh9f4ry@gmail.com

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Sadaf Qafari

Position

Intern

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

Street address

No.26; 120 alley; Daraii street; Ferdowsi square

City

Kermanshah

Province

Kermanshah

Postal code

6718833134

Phone

+98 83 3724 4137

Fax**Email**

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

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

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available