

# 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