

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### Investigation of physicochemical properties and clinical effects of Capsule containing standardized hydroalcoholic extract of myrtus communis L. leaves in the treatment of mild to moderate Alzheimer's disease (AD): A randomized double-blind placebo controlled trial

#### Protocol summary

##### Study aim

Clinical effects of the standardized hydro-alcoholic extract of Myrtus communis L. in mild to moderate Alzheimer's disease: (AD); a randomized double-blind placebo controlled trial

##### Design

The study groups consisted of the control group (placebo) and the intervention group (herbal medicine) and randomly assigned by random allocation software in two groups. Number of patients in each group is 25.

##### Settings and conduct

This study was designed as a double blinded placebo-controlled randomized by simple method, clinical trial which is performed after obtaining the necessary permissions and obtaining written informed consent by referring to the nursing home of Kerman. People over the age of fifty whose Alzheimer's disease is diagnosed by a neurologist based on the NINCDS-ADRDA criteria (National Institute of Neurological and Communicative Disorders and Stroke and the Alzheimer's Disease and Related Disorders Association) is evaluated by the psychologist after examination by neurology and rejection of mimicking causes such as depression by the Mini-Mental State Exam test (MMST) and clinical dementia rating (CDR). After diagnosis of laboratory tests and imaging, Alzheimer's diagnosis is selected from patients with mild to moderate Alzheimer's disease.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: -Age 50 to 80 years -MMSE score between 16 and 24 -No drug abuse and alcohol dependence -Not taking anticoagulants -Ability to answer questions and no mental problems -Exclusion criteria: - Depression

##### Intervention groups

Control group, placebo and intervention group received myrtus capsule (500 mg capsule every 8 hours) For one

month.

##### Main outcome variables

Determination of the mental status and cognitive function of patients with Alzheimer before intervention and 4 weeks after intervention in the intervention and control group.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170702034861N8**

Registration date: **2019-08-26, 1398/06/04**

Registration timing: **retrospective**

Last update: **2019-08-26, 1398/06/04**

Update count: **0**

##### Registration date

2019-08-26, 1398/06/04

##### Registrant information

##### Name

Fariba Shariffar

##### Name of organization / entity

Kerman University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 34 3132 5020

##### Email address

fshariffar@kmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

**Expected recruitment start date**

2018-11-22, 1397/09/01

**Expected recruitment end date**

2019-08-22, 1398/05/31

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Investigation of physicochemical properties and clinical effects of Capsule containing standardized hydroalcoholic extract of myrtus communis L. leaves in the treatment of mild to moderate Alzheimer's disease (AD): A randomized double-blind placebo controlled trial

**Public title**

Study of the effect of myrtus communis L.extract on Alzheimer's disease

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age 50 to 85 years MMSE score between 16 and 24 No drug abuse and alcohol dependence Not taking anticoagulants Ability to answer questions and no mental problems

**Exclusion criteria:**

depression

**Age**

From **50 years** old to **85 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider

**Sample size**

Target sample size: **50**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Patients are divided into two groups using Simple Randomization (Group 1 received Capsule containing standardized hydroalcoholic extract of myrtus communis L. leaves and group 2 received placebo). A random number table is used to equalize the number of patients in each group.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The study is double-blind, meaning that the questionnaire and the participant in the study do not know how the drug and placebo are allocated.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Kerman University of Medical Sciences

**Street address**

Shariati St. - Deputy of Research and Technology of Kerman University of Medical Sciences

**City**

kerman

**Province**

Kerman

**Postal code**

76175-493

**Approval date**

2019-01-26, 1397/11/06

**Ethics committee reference number**

IR.KMU.REC.1397.358

**Health conditions studied****1****Description of health condition studied**

Alzheimer's disease

**ICD-10 code**

G30-G32

**ICD-10 code description**

Other degenerative diseases of the nervous system

**Primary outcomes****1****Description**

- Cognitive status of patients

**Timepoint**

Before and after 4 weeks of intervention

**Method of measurement**

Mini-Mental State Exam (MMSE) and Clinical Dementia Rating (CDR)questionnaire

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: A 500 mg capsule containing an extract of myrtus communis, which was made by

Pharmacognosist at the Kerman Pharmaceutical Faculty, was received every 8 hours for four weeks.

**Category**

Treatment - Drugs

**2****Description**

Control group: A 500 mg capsule containing Starch powder, which was made by Pharmacognosist at the Kerman Pharmaceutical Faculty, was received every 8 hours for four weeks.

**Category**

Placebo

**Recruitment centers****1****Recruitment center****Name of recruitment center**

The old people`s home of Mehr Azin, Iran, Kerman

**Full name of responsible person**

Pegah Noorae

**Street address**

No.17 Alley, Motahari street

**City**

Kerman

**Province**

Kerman

**Postal code**

7618843552

**Phone**

+98 34 3311 5120

**Email**

pegahn73p@gmail.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Dr. Fariba Sharififar

**Street address**

Campus of Medical Sciences, Beginning of the axis of seven Alavi Gardens

**City**

Kerman

**Province**

Kerman

**Postal code**

7616913555

**Phone**

+98 34 3132 5700

**Email**

pegahn73p@gmail.com

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor****organization/entity?**

Yes

**Title of funding source**

Kerman 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**

Kerman University of Medical Sciences

**Full name of responsible person**

Pegah Noorae

**Position**

General pharmacy student

**Latest degree**

A Level or less

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

Faculty of Pharmacy, Campus of the University of Medical Sciences, Beginning of the axis of seven Alavi Gardens

**City**

Kerman

**Province**

Kerman

**Postal code**

7619613555

**Phone**

+98 34 3132 5600

**Email**

pegahn73p@gmail.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Fariba Sharififar

**Position**

Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

Beginning of the axis of seven Alavi Gardens, Campus of the University of Medical Sciences, Faculty of Pharmacy

**City**

Kerman

**Province**

Kerman

**Postal code**

7619613555

**Phone**

+98 34 3132 5600

**Email**

fsharififar@kmu.ac.ir

**City**

Kerman

**Province**

Kerman

**Postal code**

7619613555

**Phone**

+98 34 3132 5600

**Email**

pegahn73p@gmail.com

**Person responsible for updating data****Contact****Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Pegah Noorae

**Position**

General pharmacy student

**Latest degree**

A Level or less

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

Beginning of the axis of seven Alavi Gardens, Campus of the University of Medical Sciences, Faculty of Pharmacy

**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**

No - There is not 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**

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