Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 Sharififar

Name of organization / entity
Kerman University of Medical Sciences

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Iran (Islamic Republic of)

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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)questionnair

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 Nooraee

Street address

No.17 Alley, Motahari street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Dr. Fariba Sharififar

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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

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 Nooraee

Position

General pharmacy student

Latest degree

A Level or less

Other areas of specialty/work

Medical Pharmacy

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Latest degree

Ph.D.

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Person responsible for updating data

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Kerman University of Medical Sciences
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Position
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Latest degree
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Other areas of specialty/work
Medical Pharmacy
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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
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