

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Clinical study of the effect of standard hydroalcoholic extract of (Zataria multiflor) aerial parts on Alzheimer's disease.

Protocol summary

Study aim

Determination of the effect of standard hydroalcoholic extract of aerial parts of Avishan shirazi on Alzheimer's disease severity.

Design

After diagnosis of mild to moderate Alzheimer's, subjects are randomly divided into placebo and intervention groups. The control group received placebo and the Avishan Shirazi capsule intervention group. In the form of soy capsules, a 600-mg capsule should be given every 6 hours (2.4 g daily dose). The control group also received a 600 mg capsule without extracts Receive every 6 hours for one month.

Settings and conduct

This study was designed as a randomized clinical trial of Shahandar-doorkour which is carried out after obtaining the necessary permissions and obtaining written informed consent by visiting the nursing home of Kerman.

Participants/Inclusion and exclusion criteria

For the study of people over the age of fifty years who have been diagnosed with Alzheimer's disease by a neurologist based on the NINCDS-ADRDA criteria, and after this clinical interview, a neurological examination of psychological tests is performed from patients. In this method, patients with mild Alzheimer's disease They are selected to an average.

Intervention groups

The intervention group received capsules containing Avishan shirazi extract powder (600 mg capsule every 6 hours). The dose of the drug is 2.4 grams per day. The control group received 600 mg of starch powder capsules every 6 hours for 8 weeks.

Main outcome variables

Determination of mental status and cognitive function of patients with Alzheimer's disease before intervention, four weeks and eight weeks later in intervention and control group

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170702034861N10**

Registration date: **2019-12-09, 1398/09/18**

Registration timing: **registered_while_recruiting**

Last update: **2019-12-09, 1398/09/18**

Update count: **0**

Registration date

2019-12-09, 1398/09/18

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

2019-12-06, 1398/09/15

Expected recruitment end date

2020-05-04, 1399/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical study of the effect of standard hydroalcoholic extract of (*Zataria multiflora*) aerial parts on Alzheimer's disease.

Public title

Study of the effect of *Zataria multiflora* on Alzheimer's disease.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 50 to 85 years MMSE score between 16 and 24
Ability to answer questions and no mental problems

Exclusion criteria:

drug abuse and alcohol dependence taking
anticoagulants depression

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization of this study was performed by a quadratic block design by Random allocation software and a vital statistics expert. Subjects with mild to moderate Alzheimer's disease and having appropriate conditions were divided into intervention and control groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

This is a double-blind study, meaning that the questioner and study participant do not know whether a person is in the drug group or placebo.

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

Deputy of Research and Technology of Kerman
University of Medical Sciences, Shariati Street.

City

Kerman

Province

Kerman

Postal code

76175493

Approval date

2019-08-25, 1398/06/03

Ethics committee reference number

IR.KMU.REC.1398.255

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 600 mg capsule containing an extract of *Zataria multiflora*, which was made by Pharmacognosist at the Kerman Pharmaceutical Faculty, was received every 6 hours for four weeks.

Category

Treatment - Drugs

2

Description

Control group a 600 mg capsule containing Starch powde , which was made by Pharmacognosist at the Kerman Pharmaceutical Faculty, was received every 6 hours for four weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

مراکز نگهداری سالمندان

Full name of responsible person

Kosar Sargazi Moghadam

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Faculty Pharmacy, Campus of the University of
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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

Kosar Sargazu moghadam

Position

General Pharmacy student

Latest degree

A Level or less

Other areas of specialty/work

Medical Pharmacy

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Faculty Pharmacy, Campus of the University of
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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Fariba Sharififar

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

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Full name of responsible person

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Position

General pharmacy student

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

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