

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

Clinical evaluation of the effect of standard hydroalcoholic extract of soybean seeds (*Glycine max L.*) on Alzheimer's disease severity.

Protocol summary

Study aim

Determination of the effect of standard hydroalcoholic extract of soybean (*Glycine max L.*) seeds 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 soy capsule intervention group. In the form of soy capsules, a 500-mg capsule should be given every 8 hours (0.5 g daily dose). The control group also received a 500 mg capsule without extracts Receive every 8 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 soybean seeds extract powder (500 mg capsule every 8 hours). The dose of the drug is 1.5 grams per day. The control group received 500 mg of starch powder capsules every 8 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: **IRCT20170702034861N9**

Registration date: **2019-10-18, 1398/07/26**

Registration timing: **registered_while_recruiting**

Last update: **2019-10-18, 1398/07/26**

Update count: **0**

Registration date

2019-10-18, 1398/07/26

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

2019-07-23, 1398/05/01

Expected recruitment end date

2019-10-22, 1398/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical evaluation of the effect of standard hydroalcoholic extract of soybean seeds (*Glycine max L.*) on Alzheimer's disease severity.

Public title

Effect of Soybean on Alzheimer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 50 years old Having a MMSE score between 16 and 24 Lack of substance abuse and alcohol abuse Do not use anticoagulants Lack of heart disease

Exclusion criteria:

depression

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

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 biostatistics specialist. 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

The study is double-blind, meaning the researcher and study participants do not know who is in the drug group and who is in the placebo group.

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 St.

City

Kerman

Province

Kerman

Postal code

76175-493

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

90-60-0day

Method of measurement

MMSD and CDR questionnair

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group will receive the soybean capsule. Get help with the capsule shape You can eat in your 500ml capsule every 8 hours.

Category

Treatment - Drugs

2

Description

Control group: The placebo group received starch every 8 hours for three months.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

The old people's homes

Full name of responsible person

Zeynab Pour Ramazan

Street address

Beginning of the Axis of the Seven Gardens of Alavi,
Campus of the University of Medical Sciences,
Kerman, Iran

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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

Zeynab Pour Ramezan

Position

General Pharmacy student

Latest degree

A Level or less

Other areas of specialty/work

Medical Pharmacy

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professor

Latest degree

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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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