Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 capsuls 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 Sharififar

Name of organization / entity
Kerman University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 34 3132 5020

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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:
depession
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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7616913555

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
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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

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Ph.D.

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Person responsible for updating data

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Position
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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