Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Evaluation of the effectiveness of herbal mixture based on Boswellia in improving cognitive and behavioral disorders in patients with mild to moderate Alzheimer's disease ,A Randomized Double-Blind Clinical Trial with Placebo-Controlled.

Protocol summary

Study aim
The effect of Boswellia-based herbal capsules on improving cognitive-behavioral disorders in Alzheimer's patients Mild to moderate

Design
Clinical trial with control group, with parallel groups, double-blind, Randomized is phase 3 which is performed in 64 patients with mild to moderate Alzheimer's disease in Roozbeh Hospital.

Settings and conduct
This study will be performed on patients with mild to moderate Alzheimer's disease referred to Roozbeh Hospital for 3 months. Patients receive herbal capsules or placebo three times a day for 3 months at random. The herbal capsule does not change the dose of these drugs as much as possible. The specific code of each patient is written on the research label of each capsule package, which is opaque. Due to the fact that the control drug packages and the test drug are completely similar and also random codes are used to identify them, patients will not be informed about the type of drug they are receiving.Also, according to the identity codes of each patient that is created at the beginning of the study, the study data will be provided anonymously to the study results analysis team. Thus, the study is blinded for the patient and the evaluator.

Participants/Inclusion and exclusion criteria
The study population in this study is people over 50 years of age who have been diagnosed with mild to moderate Alzheimer's disease based on a DSM-V-based clinical neurologist interview. These patients have at least a basic education.

Intervention groups
Patients with mild to moderate Alzheimer's disease in two groups of 32 people Random is divided into two groups of drugs and placebo. Both groups receive herbal capsules 3 times a day with each meal.

Main outcome variables
Effect on improving cognitive and behavioral disorders

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210701051755N1**
Registration date: **2021-09-16, 1400/06/25**
Registration timing: **prospective**

Last update: **2021-09-16, 1400/06/25**
Update count: **0**

Registration date
2021-09-16, 1400/06/25

Registrant information

Name
Mahsa Panahishokouh

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-09-21, 1400/06/30

Expected recruitment end date
2022-02-19, 1400/11/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effectiveness of herbal mixture based on Boswellia in improving cognitive and behavioral disorders in patients with mild to moderate Alzheimer's disease ,A Randomized Double-Blind Clinical Trial with Placebo-Controlled.

Public title
Evaluation of the effectiveness of Boswellia -based herbal powder mixture in improving of Alzheimer's patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
people over 50 years old who have been diagnosed with mild to moderate Alzheimer's disease based on a clinical interview with a DSM-V neurologist Minimum primary education
Exclusion criteria:
Major psychiatric disorders such as depression, schizophrenia; psychotic disorders Other causes of dementia include pure vascular dementia, airway dementia, and frontotemporal dementia. Treatable causes of dementia such as metabolic disorders Patients with severe hepatic impairment (Child-Pugh class c), renal (GFR <25 ml / min) and cardiac (EF <15%) Taking the drug memantine Taking any medication or herbal supplement with an effect on cognitive function Reluctance to continue the plan, at any time and for any reason during the study Serious side effects during treatment
Age
From **50 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **64**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization by random block method, randomization with 4 blocks, and using Random Allocation Software will be specified from the random number table. Blocking and allocation sequencing for concealment will be done by the person not involved in the research. The allocation ratio of the samples was Allocation 1: 1 and they will be placed in two groups receiving herbal capsules and placebo. The sequence of allocation, drugs will be given to patients.
Blinding (investigator's opinion)
Double blinded
Blinding description
This study is designed to be double-blind. labeling Research will be done on two products. All case medications Consumption in the closed study was completely opaque and in them with The disposable label will be packaged. On this code pack Corresponding to randomization is inserted. Thus the effect and the doctor Investigator of clinical implications of increased allocation in treatment groups.It was accepted that at the end all the data is encrypted The direction of analysis will be increased.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Institute of Pharmaceutical Sciences, Tehran University of Medical Sciences
Street address
Poursina St., Tehran University of Medical Sciences, Faculty Pharmacy, Institute of Pharmaceutical Sciences (TIPS), (PO Box). 14176-13151, Iran
City
Tehran
Province
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Postal code
14176-13151
Approval date
2021-09-12, 1400/06/21
Ethics committee reference number
IR.TUMS.TIPS.REC.1400.115

Health conditions studied

1

Description of health condition studied
Mild to moderate Alzheimer's
ICD-10 code
G30
ICD-10 code description
Alzheimer's disease

Primary outcomes

1

Description
Score of cognitive disorders in MMSE, MOCA questionnaires
Timepoint
3 months from the start of the study
Method of measurement
MMSE(Mini–mental state examination), MOCA(montreal cognitive assessment)

2

Description
Behavioral Disorders Score in NPI Questionnaire
Timepoint
3 months from the start of the study
Method of measurement
(Neuropsychiatric Inventor)NPI test

Secondary outcomes

1

Description
Investigation of side effects
Timepoint
monthly
Method of measurement
Ask questions of the patient and record information

Intervention groups

1

Description
Intervention group: 3 packs of 30 oral herbal capsules of 500 mg (Boswellia as the main component about 160 mg, physalis or puppet behind the curtain, cinnamon and peppermint 14 mg each and about 240 mg of sugar) three times a day, With every meal, for 3 months, By partner laboratories of the Ministry of Health and Medicinal Plants Research Institute
Category
Treatment - Drugs

2

Description
Control group: 3 packs of 30 oral placebo capsules, three times a day, With every meal, for 3 months, By partner laboratories of the Ministry of Health and Medicinal Plants Research Institute
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Roozbeh Psychiatric Hospital
Full name of responsible person
Mahsa Panahishokouh
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South Kargar Street, below the Lashgar intersection
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Sponsors / Funding sources

1

Sponsor
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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
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Mahsa Panahishokouh

Position
Resident of Clinical Pharmacy

Latest degree
Medical doctor

Other areas of specialty/work
Medical Pharmacy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
Because of confidentiality

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not 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