

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)

Phone

+98 21 2213 2705

Email address

mahsapanahishokooh@gmail.com

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

Tehran

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

Street address

South Kargar Street, below the Lashgar intersection

City

Tehran

Province

Tehran

Postal code

13337159140

Phone

+98 21 5541 9151

Email

r.ac.tums@roozbeh_hosp

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraeian

Street address

Keshavarz Boulevard, corner of Quds Street, Central University Organization, sixth floor, Vice Chancellor for Research and Technology

City

Tehran

Province

Tehran

Postal code

1417653911

Phone

+98 21 8163 3698

Email

r.ac.tums@vc

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

Street address

Saadat Abad, Sarv Intersection, Payam Blvd., Shahid
Ahangrani St., Pasargad Town, Block 40, Third Floor

City

Tehran

Province

Tehran

Postal code

1981819646

Phone

+98 21 2213 2705

Email

mahsapanahishokoooh@ gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Niayesh Mohebibi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

Street address

South Kargar Street, below the Lashgar intersection

City

Tehran

Province

Tehran

Postal code

13337159140

Phone

+98 21 5541 9

Email

m.yahoo@mohebibi_niayesh

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mahsa Panahishokouh

Position

Resident of pharmacotherapy

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

Street address

Saadat Abad, Sarv Intersection, Payam Blvd., Shahid
Ahangrani St., Pasargad Town, Block 40, Third Floor

City

Tehran

Province

Tehran

Postal code

1981819646

Phone

+98 21 2213 2705

Email

mahsapanahishokoooh@ gmail.com

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