

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Study of adding *Boswellia serrata* resin to therapy of patients with mild to moderate Alzheimer's disease on cognitive status compared with placebo

Protocol summary

Study aim

Evaluation of the effect of *Olibanum* resin on improvement of mild to moderate Alzheimer's disease

Design

30 sample size RCT in tow parallel group placebo&Control, Double-Blind, Block Randomization using the website www.Randomization.com

Settings and conduct

Alzheimer's patients referring to clinic of Avicenna's hospital in Mashhad if they have inclusion criteria after the signature of the informed consent form by legal guardians are randomly and double blind (such as Researchers, clinical caregivers, patients, outcome evaluator, and data analyzer) divided into two groups of 15 treatment and placebo; after Receiving capsules for 12 weeks; Mental status of both groups is studying with MMSE and CDR tests and compared to week zero Using SPSS.16 software.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with mild to moderate Alzheimer's disease based on the score of the MMSE test= 10-23 Exclusion criteria: Diagnosis of Alzheimer's disease less than 6 months before entering the study, Using cholinesterase inhibitors and / or memantine less than 90 days before entering the study or discontinuing them less than 90 days before entering the study, Use of other drugs and substances that affect cognitive status less than 60 days before entering the study or discontinued less than 90 days before entering the study, Vascular dementia, thyroid disease, vitamin B12 deficiency, anemia, Lewy body dementia, liver function disorders, brain tumors, ischemic CVA

Intervention groups

Intervention group: A capsule containing 750 mg of *Olibanum* resin is taken orally three times per day for 12 weeks. Control group: The placebo is used like *Olibanum* in the form of capsules are apparently similar to the

study drug , which contains 500 mg of starch powder. Capsules are provided by the Pharmacy Department of Herbal Drugs at Imam Reza Pharmacy in Mashhad

Main outcome variables

Cognitive status

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161219031463N2**

Registration date: **2019-03-09, 1397/12/18**

Registration timing: **retrospective**

Last update: **2019-03-09, 1397/12/18**

Update count: **0**

Registration date

2019-03-09, 1397/12/18

Registrant information

Name

Hamid Reza Sadeghnia

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3882 8566

Email address

sadeghniahr@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-09, 1397/07/17

Expected recruitment end date

2018-12-22, 1397/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of adding Boswellia serrata resin to therapy of patients with mild to moderate Alzheimer's disease on cognitive status compared with placebo

Public title

Improving effects of olibanum on learning and memory

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with mild to moderate Alzheimer's disease based on the score of the MMSE test between 10-23

Exclusion criteria:

Diagnosis of Alzheimer's disease less than 6 months before entering the study Using cholinesterase inhibitors and / or memantine less than 90 days before entering the study or discontinuing them less than 90 days before entering the study Use of other drugs and substances such as ginkgo biloba or vitamin E that affect cognitive status less than 60 days before entering the study or discontinued less than 90 days before entering the study. Vascular dementia, thyroid disease, vitamin B12 deficiency, anemia, Lewy body dementia, liver function disorders, brain tumors, ischemic cerebrovascular accidents

Age

From **55 years** old to **82 years** old

Gender

Both

Phase

2

Groups that have been masked

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

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization was done individually, block and using the website www.Randomization.com with 6 subjects per block. This was done by an independent researcher and was given to the capsule deliverer by naming the unknown letters that the person did not know the original name of the capsules named in letters.

Blinding (investigator's opinion)

Double blinded

Blinding description

Groups as participants, clinical care givers, outcome evaluators and data analyzer are not aware of the

presence of samples in the control group of the placebo or the study group. So that the duty of dividing the patients into two groups was performed by the person who was not dependent on the study, and the distribution of the drug and placebo was done by the same person, and until the end of the study, information about the grouping of patients was reserved by this person

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

The Ethics Committee of Mashhad University of Medical Sciences

Street address

Ghershi building, Daneshgah Ave.

City

Mashhad

Province

Razavi Khorasan

Postal code

91388-13944

Approval date

2016-12-18, 1395/09/28

Ethics committee reference number

IR.HUHS.REC.1395.438

Health conditions studied**1****Description of health condition studied**

Alzheimer's disease

ICD-10 code

F00

ICD-10 code description

Dementia in Alzheimer disease

Primary outcomes**1****Description**

Cognitive status

Timepoint

Study of cognitive status at the beginning of the study (before the intervention) and 12 weeks after the start of use of capsule containing Olibanum resin or placebo

Method of measurement

Using MMSE and CDR tests

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: A capsule containing 750 mg of Olibuma resin is taken orally three times per day for 12 weeks. Capsules are provided by the Pharmacy Department of Herbal Drugs at Imam Reza Pharmacy in Mashhad

Category

Treatment - Drugs

2

Description

Control group: The placebo is used in the form of capsules are apparently similar to the study drug , which contains 500 mg of starch powder three times a day for 12 weeks orally. Capsules are provided by the pharmacy department of Herbal Drugs at Imam Reza Pharmacy in Mashhad

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ebne Sina hospital

Full name of responsible person

Ali Manteghi

Street address

Next to Astan Ghods Razavi's transition, Horr Ameli Blv.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Ghershi building, Daneshgah Ave.

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Web page address

<http://v-research.mums.ac.ir/index.php/moaven/tafaghodim>

Grant name

940998

Grant code / Reference number

940998

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Hamid Reza Sadeghnia

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Pharmacology Department, Faculty of Medicine, Inside campus college, Azadi square

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Sadeghniahr@mums.ac.ir

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<http://pharmacodept.mums.ac.ir>

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Hami Reza Sadeghnia

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Hamid Reza Sadeghnia

Position

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Latest degree

Ph.D.

Other areas of specialty/work

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Web page address

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Demographic data, MMSE and CDR tests' scores

When the data will become available and for how long

Start the access period 6 months after Releasing the results

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

For use in complementary studies including repeat study with higher sample size

From where data/document is obtainable

Dr Hamid Reza Sadeghnia, Mashhad Faculty of Medicine, Department of Pharmacology Email: Sadeghniahr@mums.ac.ir Fax: +98 51 3882 8567 Address: Pharmacology Department, Faculty of Medicine, Inside campus college, Azadi square Postal code: 91388-13944

What processes are involved for a request to access data/document

Submit a formal and written request from the Research, Academic and Scientific Institute at the address above

Comments

No comments