Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 websitewww.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 doubel 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 than90 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)

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+98 51 3882 8566

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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 analyser

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 indipendent 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 paticpants, 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
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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
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Person responsible for scientific inquiries

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Associate Professor

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Person responsible for updating data

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Email
Sadeghniahr@mums.ac.ir

Web page address
http://pharmacodept.mums.ac.ir

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