

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Explanation of "Nesyan" in Iranian traditional medicine and study of effects of extract of *Nepeta menthoides* Boiss and Buhse on cognitive disorders in dementia a double blind clinical trial with placebo

Protocol summary

Summary

Dementia as a chronic progressive disorder is one of the main causes of disability in the old age that is associated with an epidemic and significant increase in recent years. The main symptom of dementia is progressive forgetfulness that gradually leads to disorders in thinking, judgment, orientation, learning, language, behavior and mood. Treatments include psychological therapies (cognitive, behavioral and supportive therapy) or cholinesterase inhibitors, NMDA receptor agonist and psychotropic drugs. In addition to the complications of medications, we have little Improvement and no effect on the course of the disease. That is why the traditional and complementary approaches have been developed . The word "Nesyan" in traditional term means to forget what was learned or inability to learn, which is similar to the modern concept of dementia. The cause in traditional term is dysfunction of the cerebral forces (Memory, thinking and imagination). "Ostokhodus" according to Iranian sages is a unique drug in empowering the brain, very effective in purification and purification, Nourishing mental and intellectual forces and useful in neuronal diseases. Recent studies in animal models proved it as a heating, antioxidant herbal remedy with anti-cholinesterase inhibitory effects. Therefore, this medicinal species selected to prove its effectiveness in human studies.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015051022195N1**
Registration date: **2015-11-15, 1394/08/24**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-11-15, 1394/08/24

Registrant information

Name

azam abdolahadi

Name of organization / entity

traditional faculty of shahid beheshti medical university

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2015-07-23, 1394/05/01

Expected recruitment end date

2016-03-10, 1394/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Explanation of "Nesyan" in Iranian traditional medicine and study of effects of extract of *Nepeta menthoides* Boiss and Buhse on cognitive disorders in dementia a double blind clinical trial with placebo

Public title

Effects of *Nepeta menthoides* Boiss and Buhse on cognitive disorders in Dementia

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Age 65 to 85 years; Dementia diagnosis based on the baseline MMSE score less than 20 in the questionnaire by the psychiatrist; Have at least five classes of literacy; Obtain informed consent from the patient or the patient's guardian; No psychiatric disorder other than Alzheimer's disease according to a specialist such as depression and other diseases; Lack of substance abuse or drugs (except nicotine and caffeine); AChE inhibitors allergy history; History of heart disease, seizure, asthma, peptic ulcer, urinary tract obstruction; Reporting the warmth of humor based on valid and reliable questionnaire doctor Mujahid. Exclusion criteria: Drug side effects; Tend to withdraw from the project at any stage of the investigation.

Age
From **65 years** old to **85 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Shahid Beheshti University of Medical Sciences

Street address
7th Floor , 2nd SBUMS Bldg. ,Next to Ayatollah Taleghani Hospital, Evin , Tehran, Iran. Post code: 198396-3113

City
Tehran

Postal code
198396-3113

Approval date
2015-01-04, 1393/10/14

Ethics committee reference number
163

Health conditions studied

1

Description of health condition studied

Mental and behavioural disorders

ICD-10 code

F03

ICD-10 code description

Unspecified dementia

Primary outcomes

1

Description

Cognitive state

Timepoint

In the beginning and the end of prescription and three months following the treatment

Method of measurement

Mini Mental State Exam(folstein)

Secondary outcomes

1

Description

Side effects

Timepoint

During and three months after the treatment

Method of measurement

Symptoms and signs by the physician

Intervention groups

1

Description

Extract of *Nepeta menthoides* Boiss and Buhse in the form of 500 mg capsules three times in a day in the intervention group

Category

Treatment - Drugs

2

Description

Starch in the form of 500 mg caps three times a day in the control group

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Iran Alzheimer's Association
Full name of responsible person
Ali Nazeri
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Ekbatan, Basij Square, North nursing the sattari exit,
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Person responsible for scientific inquiries

Contact

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Sponsors / Funding sources

1

Sponsor

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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
School of Traditional Medicine, Shahid Beheshti
University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty