

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Evaluation of the effectiveness of "Prunus dulcis" on Alzheimer's diseases

Protocol summary

Study aim

Determination and comparison of MMSE and FAST, CDR and MoCA questionnaires and the sleep questionnaire of sweet almond recipients in Alzheimer's patients

Design

Clinical trial with control group with parallel groups, without blinding, randomized, 2 groups on 60 patients. Allocation concealment was used for concealment.

Settings and conduct

This research is designed as a clinical trial to investigate the therapeutic effect of sweet tree almonds on Alzheimer's patients. Patients diagnosed with the disease by a psychiatrist or neurologist or geriatric medicine specialist at the Iranian Alzheimer's Association complete the relevant questionnaires at the beginning and at the end of the study and receive almonds with a specific dose during the study for three months. The control group without receiving almonds, completes the questionnaire at the beginning and end of the study.

Participants/Inclusion and exclusion criteria

"Entry conditions": 1. Patients with Alzheimer's disease ; 2. Not having other psychiatric disease causing dementia other than Alzheimer's; 3. Not having severe non-psychiatric and non-neurological diseases; 4. Not abusing substances or drugs such as narcotics or stimulants; 5. Completion of written informed consent of the patient or the patient's guardian to enter the plan; "Non-entry conditions": 1. Uncontrolled diabetes mellitus because the almonds are slightly sweetened with candy

Intervention groups

patients with mild to moderate Alzheimer's disease diagnosed as the intervention group, receive tree sweet almonds with a specified dose, and questionnaires are completed at the beginning and end of the study. Due to the open label nature of the study, the control group without receiving sweet almonds fills the questionnaires at the beginning and at the end of the study.

Main outcome variables

Change in score of MMSE and FAST ,CDR and MoCA and sleep questionnaire

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231031059912N1**

Registration date: **2024-01-22, 1402/11/02**

Registration timing: **retrospective**

Last update: **2024-01-22, 1402/11/02**

Update count: **0**

Registration date

2024-01-22, 1402/11/02

Registrant information

Name

Mohsen Mohajeri

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 5558 0388

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mo_mohajeri@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-21, 1399/10/01

Expected recruitment end date

2021-12-22, 1400/10/01

Actual recruitment start date

2019-12-22, 1398/10/01

Actual recruitment end date

2023-05-22, 1402/03/01

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of "Prunus dulcis" on

Alzheimer's diseases

Public title

Studying the effect of almond on Alzheimer's disease

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients diagnosed based on history and questionnaire and examination and paraclinic under the supervision of psychiatrist or neurologist or geriatrics specialist Having no other psychiatric disease causing dementia other than Alzheimer's based on the opinion of a specialist Not having severe non-psychiatric and non-neurological diseases based on the opinion of a specialist Not abusing substances or drugs (except nicotine and caffeine) such as narcotics or stimulants Informed written consent of the patient or the patient's guardian to enter the plan

Exclusion criteria:

Uncontrolled diabetes mellitus because the almonds are slightly sweetened with candy

Age

From **60 years** old to **95 years** old

Gender

Both

Phase

0

Groups that have been masked

No information

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, we will use the block randomization method and in this two-group clinical trial, we will have 4 blocks. For each person who enters the study, a code is obtained from the software and it is determined which group (intervention or control) it belongs to. The working tool is Random Allocation Software. This software can be downloaded for free from the following address: <https://random-allocation-software.software.informer.com/2.0> In the mentioned software, the number of two groups and the sample size is 100, the block method with random sizes is selected and the output is the randomization list. In order to conceal, we use specialized random Allocation concealment, this method is such that the allocated group is not known before the individual is allocated, in this way, by using opaque envelopes marked with a random sequence, which in In this method, each of the random sequences created is recorded on a card and the cards are placed in the envelopes in order. Finally, the lids of the envelopes are glued and placed in a box. Blocking and preparation of envelopes is done by a person not involved in data sampling and analysis. In this way, the person who collects, the person who analyzes, and the person who participates do not know the type of intervention received and in which group each person is placed.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Iran University of Medical Sciences (Research Ethics Committee)

Street address

Unit 220, Second Floor, The central building of the university, Vice Chancellor for Research & Technology, Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran, IRAN

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Approval date

2020-12-13, 1399/09/23

Ethics committee reference number

IR.IUMS.REC.1399.1001

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

Alzheimer

ICD-10 code

F00.1

ICD-10 code description

Dementia in Alzheimer disease

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

Change in score of MMSE and FAST questionnaires, CDR and MoCA and sleep questionnaire

Timepoint

Completing the questionnaire at the beginning of the study (before the start of the intervention) and 3 months after starting to consume almonds

Method of measurement

MMSE, MoCA, CDR, FAST and sleep questionnaires

Secondary outcomes

1

Description

Complications

Timepoint

The time periods of completing the questionnaire as a secondary outcome, at the beginning of the study (before the start of the intervention) and 3 months after consuming almonds.

Method of measurement

MMSE and FAST, CDR and MoCA and sleep questionnaires

Intervention groups

1

Description

"Intervention group": Sweet almond obtained from central Zagros regions in the amount of 10 grams per day, slightly sweetened with cantaloupe powder (about one tablespoon) were consumed by the intervention group for three months.

Category

Treatment - Other

2

Description

"Control group": The control group does not use drugs and the questionnaire is completed only before and after the study.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Iran Dementia and Alzheimer's Association

Full name of responsible person

Ahmadzadeh

Street address

Basij Square, Ekbatan, Iran Dementia and Alzheimer's Association, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research & Technology

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

Vice Chancellor for Research & Technology

Proportion provided by this source

60

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

Iran University of Medical Sciences

Full name of responsible person

Dr. Mohsen Mohajeri

Position

assistant

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

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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

Yes - There is 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

All data is potentially shareable after de-identifying individuals

When the data will become available and for how long

The access period starts 3 months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions and other people

Under which criteria data/document could be used

There is no limit for scientific use and exploitation of the results. However, the questionnaires of people's diseases must remain completely confidential.

From where data/document is obtainable

For use, they can refer to the library website of the Faculty of Iranian Medicine, Iran University of Medical Sciences. Also, use the articles extracted from the research work and published in magazines.

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

A person should visit the library and use the results after membership or through guest membership. Also, by referring to websites related to magazines, he can access articles.

Comments