Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
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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
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Tehran
Province
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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
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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
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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