Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Efficacy of Frankincense Extract on Mild Cognitive Impairment and Evaluation of Brain-Derived Neurotrophic Factor (BDNF) as a Biomarker for Diagnosis and Monitoring of Treatment Response: A Randomized, Double-Blind, Placebo-Controlled Clinical Trial"

Protocol summary

Study aim
The effect of frankincense extract on mild cognitive impairment and evaluating brain-derived neurotrophic factor (BDNF)

Design
This study is an interventional, randomized, parallel, and double-blind clinical trial that aims to evaluate the effectiveness of frankincense and investigate the role of BDNF as a biomarker for monitoring response to treatment in patients with mild cognitive impairment (MCI).

Settings and conduct
Sabzevar - This study is a randomized, parallel, and double-blind clinical trial in which patients with MCI, after screening, are randomly assigned to the frankincense or placebo group. BDNF levels and cognitive function are measured and compared at the beginning of the study and after the intervention.

Participants/Inclusion and exclusion criteria
Individuals referred to specialized neurology clinics or nursing homes with a diagnosis of MCI based on Petersen or DSM-5-TR criteria and MoCA/MMSE standard.
Exclusion criteria during the study: Definite diagnosis of dementia, severe depression, use of known BDNF-altering drugs (e.g., some antidepressants at higher doses) in the last 3 months, active systemic inflammatory disease, severe liver/kidney impairment, or known allergy to Boswellia frankincense.

Intervention groups
Standardized Boswellia spp. product (e.g., boswellic extract with a specified percentage of AKBA) at an appropriate daily dose (based on previous clinical studies, e.g., 300–600 mg/day based on the product standard) for 12 weeks.

Main outcome variables
1.Change in serum BDNF levels 2.Cognitive function 3.Quality of life and daily functioning (ADL/IADL) 4.Safety and tolerability of frankincense supplementation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20251018067673N2**
Registration date: **2026-11-04, 1405/08/13**
Registration timing: **registered_while_recruiting**

Last update: **2026-11-04, 1405/08/13**
Update count: **0**

Registration date
2026-11-04, 1405/08/13

Registrant information

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Name of organization / entity
Hakim Sabzevari University

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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-10-23, 1405/08/01

Expected recruitment end date
2027-03-11, 1405/12/20

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Efficacy of Frankincense Extract on Mild Cognitive Impairment and Evaluation of Brain-Derived Neurotrophic Factor (BDNF) as a Biomarker for Diagnosis and Monitoring of Treatment Response: A Randomized, Double-Blind, Placebo-Controlled Clinical Trial"

Public title
Efficacy of Frankincense Extract on Mild Cognitive Impairment and Evaluation of Brain-Derived Neurotrophic Factor
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Individuals aged 50 to 75 mild cognitive impairment (MCI) based on Petersen or DSM-5-TR criteria with consistent scores on MoCA/MMSE tests, capable of cooperation informed consent
Exclusion criteria:
Definitive diagnosis of dementia severe depression active systemic underlying diseases hypersensitivity to frankincense
Age
From **50 years** old to **75 years** old
Gender
Both

Phase
1-2
Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be randomly allocated to two groups—intervention (frankincense extract) and control (placebo)—in a 1:1 ratio using randomized block randomization with a block size of 4. In each 4-patient block, two patients will be assigned to the intervention group and two to the control group, and the order of assignments within each block will be generated randomly by statistical software to ensure that the allocation sequence is unpredictable.
Blinding (investigator's opinion)
Double blinded
Blinding description
The intervention consisted of capsules containing Boswellia extract and placebo, which were identical in shape, color, size, odor, and packaging. The capsules were coded by a pharmacist or an independent investigator, and the group allocation code was kept in a sealed envelope by a third party. Randomization of participants to groups was performed using a randomization method, and the codes were not opened until the statistical analysis was completed. Cognitive assessments (MoCA/MMSE) and measurement of serum BDNF levels were performed by evaluators and the laboratory, who were unaware of the group allocation of participants. Data analysis was also performed based on anonymous codes.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Hakim Sabzevari University
Street address
Tohidshahr- Hakim Sabzevari University
City
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Razavi Khorasan
Postal code
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Approval date
2025-11-19, 1404/08/28
Ethics committee reference number
IR.HSU.REC.1404.058

Health conditions studied

1

Description of health condition studied
Mild cognitive impairment
ICD-10 code
G31.84
ICD-10 code description
Mild cognitive impairment, so stated

Primary outcomes

1

Description
Primary Outcome:Change in serum brain-derived neurotrophic factor (BDNF) levels from baseline to the end of the intervention period in patients with mild cognitive impairment.
Timepoint
Study outcomes will be assessed at two time

points:Baseline: prior to initiation of the intervention and after completion of the treatment period

Method of measurement

Serum brain-derived neurotrophic factor (BDNF) levels will be measured using blood samples by the enzyme-linked immunosorbent assay (ELISA) method with a validated commercial kit, according to the manufacturer’s instructions.

Secondary outcomes

1

Description

Change in cognitive function in patients with mild cognitive impairment, assessed by changes in MoCA and MMSE scores from baseline to the end of the intervention period.

Timepoint

1-Baseline, before initiation of the intervention2-End of the intervention period (e.g., after 8 or 12 weeks)

Method of measurement

Cognitive function will be measured using the standard Mini-Mental State Examination (MMSE) and Montreal Cognitive Assessment (MoCA) tests, administered by a trained assessor under standardized conditions.

Intervention groups

1

Description

The intervention group will receive a standardized extract of frankincense (*Boswellia* spp.)—produced by the company Giah Kala—orally at a daily dose of 5 mL, once a day for 8 weeks, in addition to their usual standard care. Data collection, involving the completion of questionnaires and the collection of blood samples, will take place at two time points: at the beginning of the study and after 8 weeks.

Category

Treatment - Drugs

2

Description

The control group receives a placebo (lactulose)—identical in appearance, color, odor, and packaging—at a dose of 5 mL once daily for 8 weeks, alongside standard routine care. Data collection, involving the completion of questionnaires and blood sampling, is conducted at two time points: at the beginning of the study and after 8 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sabzevar Diabetes Association

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

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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

Hakim Sabzevari University

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
Hakim Sabzevari university
Full name of responsible person
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Associate professor
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable