Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation the efficacy of olibanum gum in cognitive impairment of patients with mild to moderate Alzheimer disease compared to placebo

Protocol summary

Summary
Alzheimer is an age related and progressive neurodegenerative disease. It is estimated to affect approximately 35 million people in worldwide. Although approved drugs are available for the management of Alzheimer and cognitive disease, the outcomes are mostly unsatisfactory. This study is a triple blind, placebo controlled; phase 2 randomized clinical trials that effect of olibanum gum was evaluated on cognitive impairment of Alzheimer's patients. One hundred and twenty mild to moderate Alzheimer's patients are selected from Neurology Clinic of Sabzevar University of medical sciences base on MMSE Scale (Mini Mental State Exam). Participants randomized to receive olibanum gum or placebo gum for 18 weeks. They were evaluated by MMSE Scale form at the first and every 4 weeks to 18 weeks.

General information

Acronym
IRCT registration information
IRCT registration number: **IRCT2017060918951N3**
Registration date: **2017-08-19, 1396/05/28**
Registration timing: **prospective**

Last update:
Update count: **0**
Registration date
2017-08-19, 1396/05/28

Registrant information
Name
Fereshteh Ghorat
Name of organization / entity
Tehran University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source
Masterfoodeh Company

Expected recruitment start date
2017-09-30, 1396/07/08
Expected recruitment end date
2018-02-28, 1396/12/09
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation the efficacy of olibanum gum in cognitive impairment of patients with mild to moderate Alzheimer disease compared to placebo

Public title
Evaluation the efficacy of olibanum gum in Alzheimer disease
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Mild to moderate Alzheimer disease patients based on MMSE Scale. Exclusion criteria: Major depression; Sever internal disease; Ischemic heart disease; Uncontrolled hypertension; Uncontrolled diabetes ;Drug and alcohol abuse.
Age
From **60 years** old to **85 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Triple blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Sabzevar University of Medical Sciences
Street address
Sabzevar University of Medical Sciences, Shohadaye Gomnam street
City
Sabzevar
Postal code
9617913112
Approval date
2017-06-07, 1396/03/17
Ethics committee reference number
Medsab.Rec.96.13

Health conditions studied

1

Description of health condition studied
Alzheimer disease
ICD-10 code
G30
ICD-10 code description
Alzheimer disease

Primary outcomes

1

Description
Cognitive function
Timepoint
Weeks of 0, 4, 8, 16, 18
Method of measurement
Mini Mental State Exam (MMSE)

Secondary outcomes

1

Description
Memory
Timepoint
Weeks of 0, 4, 8, 12, 16, 18
Method of measurement
W.M.S scale

Intervention groups

1

Description
Intervention: Olibanum gum, Three time in day
Category
Treatment - Drugs

2

Description
Control: Simple gum, Three time in day
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Neurology Clinic of Sabzevar University of Medical Sciences
Full name of responsible person
Fereshteh Ghorat
Street address
Clinic of Sabzevar University of Medical Sciences, AsadAbadi Street
City
Sabzevar

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Masterfoodeh company
Full name of responsible person
Nima Razmgoo
Street address
Number 54, Asadabadi Street, Yosef Abad, Tehran
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Masterfoodeh company
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

Contact
Name of organization / entity
Scientific Association of Traditional Medicine
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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