Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Jul 2026

Efficacy of short term consumption of Chlorella Vulgaris as an additive on severity of depression, anxiety and stress in elderly patients compared to control group

Protocol summary

Study aim
To examine the effect of Chlorella Vulgaris on depression, anxiety and stress experienced by the elderly depressed patients

Design
A parallel, triple-blind randomized trial with a control group with 80 patients in phase 3 will be conducted, Randomization was carried out using a random function in excel

Settings and conduct
All participants 60 to 80 years of age with the diagnosis of major depression from Amin hospital, Esfahan will be included, Double blinded, parallel study in which the experimental group will receive chlorella and the control group placebo, with their standard anti depressants. Neither the participants nor the research team will be unaware of the contents of the capsules until the study ends.

Participants/Inclusion and exclusion criteria
Inclusion Criteria include: Patients within the age range of 60-80 years; Reading and writing ability; Iranian nationality and ability to speak Persian; Living with at least one family member; Written consent from patient or family member; Diagnosis of major depression based on DSM-V criteria certified by the research director (psychiatrist) that the patient has not been treated for depression at least in the past 4 weeks; Exclusion Criteria include: Any serious cognitive disorder; Developing any unpredictable and undesired physical or mental problem during treatment; Consuming Warfarin and chemotherapeutic agents such as; Azathioprine, Basiliximab, Cyclosporine, Daclizumab, Muromonab-CD3, Mycophenolate, Tacrolimus; History of drug and alcohol abuse; Uncontrolled diabetes or thyroid problem;

Intervention groups
Chlorella Vulgaris is administered as an additive along with their standard antidepressants prescribed while the control group will receive placebo along with their standard antidepressants prescribed

Main outcome variables
Severity of depression, anxiety and stress

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20161010030255N5**
Registration date: **2022-06-18, 1401/03/28**
Registration timing: **prospective**

Last update: **2022-06-18, 1401/03/28**
Update count: **0**

Registration date
2022-06-18, 1401/03/28

Registrant information

Name
Victoria Omranifard

Name of organization / entity
Isfahan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-06-22, 1401/04/01

Expected recruitment end date
2022-10-22, 1401/07/30

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

Scientific title
Efficacy of short term consumption of Chlorella Vulgaris as an additive on severity of depression, anxiety and stress in elderly patients compared to control group

Public title
Efficacy of Chlorella Vulgaris in Elderly Depressed Patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients within the age range of 60-80 years Reading and writing ability Iranian nationality and ability to speak Persian Living with at least one family member Written consent from patient or family member Diagnosis of major depression based on DSM-V criteria certified by the research director (psychiatrist) that the patient has not been treated for depression at least in the past 4 weeks
Exclusion criteria:
Any serious cognitive disorder Developing any unpredictable and undesired physical or mental problem during treatment Consuming Warfarin and chemotherapeutic agents such as; Azathioprine, Basiliximab, Cyclosporine, Daclizumab, Muromonab-CD3, Mycophenolate, Tacrolimus History of drug and alcohol abuse Uncontrolled diabetes or thyroid problem
Age
From **60 years** old to **80 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients who fulfill the required criteria will be selected and will be divided in blocks of two, then they will be sorted based on their national ID number. Based on random numbers the first and second place in each block will be decided. For example for numbers 0-4 the first person will be assorted the letter A and the second person will be assorted the letter B and if numbers 5-9 appear the first person will be assorted the letter B and the second person will be assorted the letter A.
Blinding (investigator's opinion)
Triple blinded
Blinding description
Capsules containing Chlorella Vulgaris and placebo are similar in color and are also packed in similar bottles labeled A and B, filled up by an anonymous person unknown to the participants and the research team. lHowever, the participants will be aware of the study process and will enter the study after written consent, but they will not know whether they have received the capsule containing chlorella or placebo until the study ends.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan university of medical sciences
Street address
No 18, Sepehr complex, Sanayeh dead end, Makine khajoo street, Charbagh khajoo street
City
Isfahan
Province
Isfehan
Postal code
8143944191
Approval date
2022-04-26, 1401/02/06
Ethics committee reference number
IR.ARI.MUI.REC.1401.018

Health conditions studied

1

Description of health condition studied
Major depression
ICD-10 code
F33.9
ICD-10 code description
Major depressive disorder, recurrent, unspecified

Primary outcomes

1

Description
Severity of depression based on Geriatric Depression

Scale (GDS)

Timepoint

Baseline data, after 6 and 12 weeks

Method of measurement

Persian version of Geriatric Depression Scale (GDS)

2

Description

Severity of depression based on Depression, Anxiety, Stress Scales (DASS)

Timepoint

Baseline data, after 6 and 12 weeks

Method of measurement

Persian version of Depression, Anxiety, Stress Scales (DASS)

3

Description

Severity of anxiety based on Depression, Anxiety, Stress Scales (DASS)

Timepoint

Baseline data, after 6 and 12 weeks

Method of measurement

Persian version of Depression, Anxiety, Stress Scales (DASS)

4

Description

Severity of stress based on Depression, Anxiety, Stress Scales (DASS)

Timepoint

Baseline data, after 6 and 12 weeks

Method of measurement

Persian version of Depression, Anxiety, Stress Scales (DASS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Elderly patients aged 60 to 80 years old diagnosed with depression will be treated with 300 - 1200 milligrams of chlorella vulgaris for 12 weeks with their standard anti depressants. As a powder chlorella vulgaris is distributed by Fardaye Sabz Iranian.

Category

Treatment - Drugs

2

Description

Control group: Elderly patients aged 60 to 80 years old diagnosed with depression will be receive 300 - 1200 milligrams of placebo for 12 weeks with their standard anti depressants

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amin Hospital, Isfahan, iran

Full name of responsible person

Doctor Victoria Omaranifard

Street address

No 18, Sepehr complex, Sanayeh dead end, Makine khajoo street, charbaghkhajoo street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Siyavash, Deputy of research, Isfahan University of Medical Sciences

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Grant name

Research grant, Isfahan university of medical sciences

Grant code / Reference number

56615

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Esfahan University of Medical Sciences

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
Esfahan University of Medical Sciences
Full name of responsible person
Dr. Victoria Omranifard
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Psychiatrics
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Patients information is confidential
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
Information regarding the type of capsule consumed (Chlorella or placebo) and its effect will be revealed
When the data will become available and for how long
After study is complete
To whom data/document is available
Data will be revealed to all researchers
Under which criteria data/document could be used
For future research
From where data/document is obtainable
In order to access relative information one can visit research director Dr. Vicrotria Omranifard in geriatric department of Amin hospital located in Ebn sina road, Sonbolestan street, Esfahan, Iran or they can contact 00983131122020 or email the research director whose address is v_omranifard@med.mui.ac.ir

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

An official request to research director

Comments