

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

Country

Iran (Islamic Republic of)

Phone

+98 31 3222 2475

Email address

v_omranifard@med.mui.ac.ir

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

AgeFrom **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 sizeTarget 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. However, 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

Isfahan

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
City
Isfahan
Province
Isfahan
Postal code
8143944191
Phone
+98 31 3223 4552
Email
sarinaght@gmail.com

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
Street address
Isafahan university of medical sciences, Hezar jarib street
City
Isfahan
Province
Isfahan
Postal code
8174673461
Phone
+98 31 3668 8789
Email
vcr-office@med.mui.ac.ir
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

Street address

EDC, Hezar jarib street, Isfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 8789

Email

v_omranifard@med.mui.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Victoria Omaranifard

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

Street address

Isfahan university of medical sciences, Hezar jarib street, Isfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3222 2475

Email

v_omranifard@med.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Victoria Omranifard

Position

Associate professor

Latest degree

Specialist

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Psychiatrics

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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. Victoria Omranifard in geriatric department of Amin hospital located in Ebn sina road, Sonbolstan 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