

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Clinical trial to evaluate the effect of photobiomodulation on cognitive and psychological tests in patients with Alzheimer's disease

Protocol summary

Study aim

The effect of photobiomodulation on cognitive and psychological tests in people with Alzheimer's disease

Design

Clinical trial with control group, with parallel, double-blind, randomized, phase 1 groups on 12 patients. Block randomization was used for randomization

Settings and conduct

The study group consists of 12 patients with mild to moderate Alzheimer's disease (based on DSM-V). Is obtained. This study will be performed in Shohada Tajrish Hospital in the years 1399-1400. Of these, 6 are treated with sham and 6 are treated with photobiomodulation for 12 weeks (randomization will be done using block randomization). How to use the device daily, for 20 minutes each time. The sessions will be conducted at home and the entire session will be viewed and recorded online by the researcher. The control group will not have any information about the status of the device on or off. Follow-up of the effectiveness of this method is 6 weeks and 12 weeks from the start of the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: mild to moderate Alzheimer's disease, conscious satisfaction, ability to walk Exclusion criteria: severe Alzheimer's disease, other known neurodegenerative diseases, previous history of extensive stroke

Intervention groups

6 people will be treated with sham and 6 others will be treated with photobiomodulation for 12 weeks (randomization method will be done using block randomization method). How to use the device daily for 20 minutes each time. The sessions will be conducted at home and the entire session will be viewed and recorded online by the researcher. The control group will not have any information about the status of the device on or off.

Main outcome variables

Age Gender DADS test MOCA test Hamilton test Illness severity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20111121008146N35**

Registration date: **2021-05-23, 1400/03/02**

Registration timing: **registered_while_recruiting**

Last update: **2021-05-23, 1400/03/02**

Update count: **0**

Registration date

2021-05-23, 1400/03/02

Registrant information

Name

Mohammadreza Razaghi

Name of organization / entity

Laser application in medical sciences research center

Country

Iran (Islamic Republic of)

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laser.cntr@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-30, 1400/02/10

Expected recruitment end date

2022-04-30, 1401/02/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial to evaluate the effect of photobiomodulation on cognitive and psychological tests in patients with Alzheimer's disease

Public title

Clinical trial to evaluate the effect of photobiomodulation on cognitive and psychological tests in patients with Alzheimer's disease

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Diagnosis of Alzheimer's disease by a neurologist

Exclusion criteria:**Age**

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: 12

Randomization (investigator's opinion)

Randomized

Randomization description

All patients are divided into case and control groups according to the table of random numbers with a ratio of 1: 1. The assigned group of individuals is placed one after the other in dark envelopes.

Blinding (investigator's opinion)

Single blinded

Blinding description

The 12 patients with Alzheimer's disease will be divided into two groups of six. In one group, placebo treatment will be performed by keeping the cap off, and in the second group, photobiomodulation treatment will be performed. Follow-up of the effectiveness of this method will be done 6 and 12 weeks after the start of the study using tests of memory, cognition and function (MOCA, DADS) and psychological tests (Hamilton Anxiety and Depression).

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shahid Beheshti University of

Medical Sciences

Street address

Laser Application in Medical Sciences Research Center, Shohadaye-Tajrish Educational Hospital, Tajrish Sq, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

1989934370

Approval date

2020-12-20, 1399/09/30

Ethics committee reference number

IR.SBMU.RETECH.REC.1399.1241

Health conditions studied**1****Description of health condition studied**

Alzheimer

ICD-10 code

f00

ICD-10 code description

Alzheimer disease is a primary degenerative cerebral disease of unknown etiology with characteristic neuropathological and neurochemical features. The disorder is usually insidious in onset and develops slowly but steadily over a period of several years.

Primary outcomes**1****Description**

DADS Test

Timepoint

At the beginning and after the end of the laser course

Method of measurement

questionnaire

2**Description**

MOCA Test

Timepoint

At the beginning and after the end of the laser course

Method of measurement

questionnaire

3**Description**

Hamilton Test

Timepoint

At the beginning and after the end of the laser course

Method of measurement

questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In addition to the usual treatment, they also use LEDs at home

Category

Treatment - Other

2

Description

Control group: This group receives only the usual treatments

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohadaye_Tajrish Hospital

Full name of responsible person

Dr. Soror Advani

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Laser Application in Medical Sciences Research Center, Shohadaye-Tajrish Educational Hospital, Tajrish Sq, Tehran, Iran.

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Laser.cntr@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Sadi Banar

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Laser Application in Medical Sciences Research Center, Shohadaye-Tajrish Educational Hospital, Tajrish Sq, Tehran, Iran.

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Maryam Barati

Position

General Practitioner

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

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Position

رزیدنت مغز و اعصاب

Latest degree

Medical doctor

Other areas of specialty/work

Neurology

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

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Latest degree

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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 unidentified individuals

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

Researchers and craftsmen

Under which criteria data/document could be used

Email the corresponding author and earn permission

From where data/document is obtainable

Email the corresponding author

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

Email the corresponding author, the authors' meeting, send the data at your discretion

Comments