

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Booster Effect of Low Level Laser Therapy On Cognitive Function in Treatment Resistant Dementia Patients

Protocol summary

Study aim

The purpose of this study is to evaluate the effect of trans-cranial low level laser therapy at infrared wavelengths of 850 nm and visible wavelength of 630 nm on treating cognitive and functional disorders in all types of primary dementia.

Design

A clinical trial with 32 patients in two groups of 16 main and randomized control and parallel and double blind groups

Settings and conduct

In memory clinic of Taleghani hospital in Tehran. 6 sessions each 10-minutes laser or sham therapy. The participant and the person assessing cognitive status before and after treatment are blinded

Participants/Inclusion and exclusion criteria

In this study, patients with at least 60 years of age who is at least two years passed from onset of their disease enter the study. Patients with a major psychiatric disorder, and with a history of head trauma, and who use benzodiazepine or have history of substance use or have claustrophobia are excluded.

Intervention groups

Both main and placebo controlled groups include patients with dementia of any type with cognitive impairment over 60 years of age without any major psychiatric disorders. The main group will be treated with low level laser and the control group will be treated with sham (same device but turned off)

Main outcome variables

Improve cognition and visiospatial function and possibly other dementia related symptoms such as sleep disturbance and depression in dementia patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191018045148N1**

Registration date: **2020-01-04, 1398/10/14**

Registration timing: **registered_while_recruiting**

Last update: **2020-01-04, 1398/10/14**

Update count: **0**

Registration date

2020-01-04, 1398/10/14

Registrant information

Name

Sonia Donboli

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4610 0558

Email address

soniadenboli@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-23, 1398/08/01

Expected recruitment end date

2020-07-22, 1399/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Booster Effect of Low Level Laser Therapy On Cognitive Function in Treatment Resistant Dementia Patients

Public title

low level laser therapy in dementia patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

age over 60 two years of illness at least dementia f all types signing the written consent form

Exclusion criteria:

with a history of a major psychiatric illness with a history of head trauma benzodiazepne use substance use claustrophobic patients

Age

From **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **32**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are randomly divided into two groups of case and control using computer software. Each of the two groups will be matched for education, age, gender, and medication use.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, participants and their care givers are unaware of which group they are in. Randomization is done by software. The person who operates laser or sham treatment for patients knows which group they are in, but the person who fills out the cognitive questionnaire for patients and cognitively examines before and after treatment is unaware of which group every patient is in.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti Medical University

Street address

Erabi street Velenjak shahid beheshti medical university

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2019-05-14, 1398/02/24

Ethics committee reference number

IR.SBMU.MSP.REC.1398.134

Health conditions studied

1

Description of health condition studied

Dementia

ICD-10 code

F03

ICD-10 code description

Unspecified dementia

Primary outcomes

1

Description

changes in scores of Clinical Dementia Rating

Timepoint

before starting the treatment with laser and at the end of the treatment and six weeks after the end of the treatment

Method of measurement

Clinical Dementia Rating (CDR)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients in this group are treated with low level laser device. This device works with red and infrared and visible light with the wavelength of 630 and 850 nm spun from 16 infrared LEDs and 16 visible light LEDs which are located in a hat connected to the device. Each individual in the main group wears the devices cap (hat) and be treated for six sessions ten minutes each in two weeks. The clinical dementia rating (CDR) questionnaire will be filled out for each patient 3 times, first before the first treatment session, second after the last treatment session and third six weeks after the last session.

Category

Treatment - Devices

2

Description

Control group: Patients in this group also like the main group will wear the device's cap for six sessions ten minutes each in two weeks but for this group the device won't be turned on in any sessions without them noticing. This is for the placebo effect. Also in this group the CDR questionnaire will be filled out for each patient 3 times, first before the first treatment session, second after the last treatment session and third six weeks after the last session.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani hospital

Full name of responsible person

Ali Kheradmand

Street address

Erabi street

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1985711151

Phone

+98 21 2303 1111

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soniaddonboli@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

Erabi street Velenjak Tehran

City

Tehran

Province

Tehran

Postal code

۱۹۸۵۷۱۷۴۴۳

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soniaddonboli@gmail.com

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

Ali Kheradmand

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Latest degree

Specialist

Other areas of specialty/work

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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

no further information

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

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

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Information about the main outcome will be shared

When the data will become available and for how long

after year 1400 (2021)

To whom data/document is available

participants in the study

Under which criteria data/document could be used

participants in the study

From where data/document is obtainable

participants in the study

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

by email adress: soniaddonboli@gmail.com

Comments