Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Therapeutic effects of low-level laser therapy in reducing obsessive compulsive disorder symptoms in bipolar patient treatment Compared with the control group

Protocol summary

Study aim

Therapeutic effects of LLLT in reducing ocd symptoms compared with the control group

Design

A clinical trial with a control group, 30 patients with OCD and definitive diagnosis of the level of OCD by questionnaire (YBOCS) and the method of randomization is also done as block randomization.

Settings and conduct

This study will be conducted in the psychiatry department of SBMU. One group will be treated with low level laser for 4 weeks and 9 sessions. The control group is also treated with a device with zero intensity in 4 weeks. The patients and I were blinded in the study, and the third person, who is a colleague of the psychologist, acted as an intermediary between the patients based on age, sex, dosage of drugs consumed and equivalent, duration of obsession.The level of education, marital status, duration of disease onset, previous hospitalization rate, type of drug and their equivalent dose are divided in such a way that there is almost a similar sample in the other group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: outpatients under treatment for OCD, over 18 years old without claustrophobia and psychosis with 2 month medication stabilization. Exclusion criteria: unwillingness to cooperate, complications in patients, patients with a history of neurological diseases, pregnancy or acute and chronic physical illness and receive ECT.

Intervention groups

Two homogeneous groups of 30 patients in a treatment group and a control group. The first group will be formed by patients who will receive laser therapy in the first 4 weeks of outpatient visits, and the second group will be selected as a control group similar to the first group.

Main outcome variables

Average score of obsessive thoughts and behaviors
Average score of anxiety Obsessive compulsive disorder symptoms

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230815059151N1**
Registration date: **2023-10-14, 1402/07/22**
Registration timing: **prospective**

Last update: **2023-10-14, 1402/07/22**
Update count: **0**

Registration date

2023-10-14, 1402/07/22

Registrant information

Name

Ali Faghfouri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8846 9459

Email address

ali_md07@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-23, 1402/08/01

Expected recruitment end date

2024-03-20, 1403/01/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Therapeutic effects of low-level laser therapy in reducing obsessive compulsive disorder symptoms in bipolar patient treatment Compared with the control group

Public title
Investigating the effect of low-level laser in reducing obsessive-compulsive symptoms
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients undergoing OCD treatment are referred to a psychiatric clinic as outpatients Age above 18 years No claustrophobia Patients should be in drug stabilization for at least 2 months The patient is not psychotic
Exclusion criteria:
Patients with a history of neurological disease such as epilepsy Having other neurological disorders such as parkinsonism Traumatic brain injury Brain stroke pregnancy Acute and chronic physical illness Cases receiving antidepressant treatment or ECT (convulsive therapy with electroshock).
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
The patients and the researcher are blinded in the study and the third party arranges the samples in two groups in such a way that in terms of age and sex, level of education, marital status, duration of the onset of the disease, the amount of previous hospitalization, the type of drug and the equivalent dose, they are almost identical. There is a similar one in another group. This third party will also place the laser device on the patient's head.
Placebo
Not 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
6th floor,Building No. 2,Shahid Beheshti University of Medical Science,Shahid Arabi,Yemen St,Shahid Chamran Highway,Tehran
City
Tehran
Province
Tehran
Postal code
193954631
Approval date
2023-06-27, 1402/04/06
Ethics committee reference number
Ir.sbmu.msp.rec.1402.155

Health conditions studied

1

Description of health condition studied
Obsessive compulsive disorder
ICD-10 code
F42
ICD-10 code description
Obsessive-compulsive disorder

Primary outcomes

1

Description
OCD severity based on the Yale-Brown Obsessive Compulsive Scale (Y-BOCS)
Timepoint
Measuring the level of obsessive compulsive disorder before the start of treatment and then at the end of treatment and one month after the last treatment in an outpatient visit to a psychiatric clinic.
Method of measurement
Yale-Brown Obsessive Compulsive Scale Questionnaire (Y-BOCS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The intervention group will be formed by patients who receive laser therapy as an adjuvant treatment in the first four weeks of outpatient visits. This group is treated with low-power laser for 9 sessions over a period of 4 weeks. 24 semi-conductor lasers with a power of 100 mW are used for laser treatment of patients, which are placed on a helmet. 12 of the lasers have a visible wavelength of 630 nm and the other 12 have a wavelength of 810 nm. The laser beam is pulsed with a frequency of 75 Hz and a duty cycle of 20 percent for 10 to 20 minutes to the scalp area of the patients. According to the diameter of the laser beam on the skull surface of the patients, which is 0.21 cm2, the power density and energy density applied to the patients in each session are 0.9 W/cm2 and 56.5 J/cm2, respectively.

Category
Treatment - Other

2

Description
Control group: The control group is treated with a silent laser device with zero intensity in the first 4 weeks of outpatient visits for 9 sessions.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Taleghani hospital

Full name of responsible person
Ali Faghfouri

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Shahid Arabi St., next to Shahid Beheshti University of Medical Science, Shahid Arabi St.,Yemen St,Shahid Chamran Highway,Tehran

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+98 21 2243 2560

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info@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Dr Afshin Zarghi

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5th floor,Building No. 2,Shahid Beheshti University of Medical Science,Shahid Arabi,Yemen St,Shahid Chamran Highway,Tehran

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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
Ali Faghfouri

Position
Psychiatry resident

Latest degree
Medical doctor

Other areas of specialty/work
Psychiatrics

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Unit 4, No 85, Hayamanesh st, Dabestan, seyyed khandan, Tehran, iran

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Person responsible for scientific inquiries

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Full name of responsible person
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Position
Psychiatry resident

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Person responsible for updating data

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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
Main outcome information and aggregate data can be shared after de-identifying individuals.

When the data will become available and for how long
Immediately after printing the results

To whom data/document is available
All researchers working in academic and scientific institutions and people working in the industry and all those interested

Under which criteria data/document could be used
By observing the ethical principles, it is possible to use the data for future research or other purposes.

From where data/document is obtainable
By phone or e-mail address (Ali_md07@yahoo.com) with the person responsible for the study

What processes are involved for a request to access data/document
Providing explanations for where and how to use data by explaining ethical protocols

Comments