

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The Effects of Low Level Laser Therapy in Cognitive Function of Chronic Schizophrenia Patients

Protocol summary

Study aim

To evaluate the Low Level Laser Therapy (LLLT) impact on cognitive impairment in institutionalized chronic schizophrenia patients

Design

A concealed, randomized, blinded, sham controlled clinical trial with a parallel group design of 32 patients

Settings and conduct

A randomized double-blind clinical trial performed among the schizophrenia patients, in a men's residential treatment centers, in Razi Psychiatric Hospital, in Tehran, Iran during the year 2020. The medically unstable patients and the ones with active suicidal idea were excluded from this survey. We screened the cognitive impairment by Mini-Mental State Examination (MMSE) and also Positive And Negative Syndrome Scale (PANSS) was used to assess the patients' positive and negative symptoms

Participants/Inclusion and exclusion criteria

All the medically stable chronic schizophrenic patients between 18-65 years old without active suicidal idea were included in this survey and the ones out of the age range and those who were medically unstable and had suicidal idea were excluded

Intervention groups

The case group will take LLLT therapy and the other group is sham controlled

Main outcome variables

The Low Level Laser Therapy (LLLT) impact on cognitive impairment and schizophrenic symptoms in institutionalized chronic schizophrenia patients will be assessed. The cognitive impairment will be checked by using the Mini-Mental State Examination (MMSE) at the base time and after treatment. The schizophrenia symptoms (positive and negative, etc) will be analyzed by Positive And Negative Syndrome Scale (PANSS) at the base time and after the treatment as well.

General information

Reason for update

Acronym

Low Level Laser Therapy (LLLT)

IRCT registration information

IRCT registration number: **IRCT20210520051349N1**

Registration date: **2021-05-24, 1400/03/03**

Registration timing: **prospective**

Last update: **2021-05-24, 1400/03/03**

Update count: **0**

Registration date

2021-05-24, 1400/03/03

Registrant information

Name

Ali Kheradmand

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-05, 1400/03/15

Expected recruitment end date

2021-08-06, 1400/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effects of Low Level Laser Therapy in Cognitive Function of Chronic Schizophrenia Patients

Public title

The effect of low level laser therapy in cognitive dysfunction and positive and negative symptoms in chronic schizophrenic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

chronic schizophrenic patients medically stable patients
no active suicidal idea or intention

Exclusion criteria:

Age

From **18 years** old to **65 years** old

Gender

Male

Phase

1-2

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **32**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation software was used to randomized the total 32 cases (according to previous similar studies).
The total 32 being allocated to 16 cases and 16 controls

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants, The main researcher, Those who assess the results

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

Taleghani Educational Hospital, Tabnak St. Velenjak Region, Chamran High Way, Tehran, Iran

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Postal code

1985711151

Approval date

2021-05-02, 1400/02/12

Ethics committee reference number

IR.SBMU.RETECH.REC.1400.067

Health conditions studied

1

Description of health condition studied

Chronic Schizophrenia

ICD-10 code

F20

ICD-10 code description

Schizophrenia

Primary outcomes

1

Description

To evaluate the Low Level Laser Therapy (LLLT) impact on cognitive impairment in institutionalized chronic schizophrenia patients

Timepoint

No meaningful difference in PANSS and MMSE test score were detected in both groups after the 6th session and 2 months after laser therapy

Method of measurement

To evaluate the LLLT impact on cognitive impairment in institutionalized chronic schizophrenia patients

Secondary outcomes

1

Description

The LLLT effects on positive and negative schizophrenic patients

Timepoint

at the base time and after the 6 th therapy session and finally 2 months after the last session

Method of measurement

PANSS questionnaire

Intervention groups

1

Description

Intervention group:

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi psychiatric hospital

Full name of responsible person

Ali Kheradmand

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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<http://sc.sbm.ac.ir/index.jsp?fkeyid=&siteid=37&pageid=12216>

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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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

6 months after the paper has been published

To whom data/document is available

who ever with Educational and therapeutic purposes

Under which criteria data/document could be used

Educational and therapeutic purposes

From where data/document is obtainable

Dr Ali kheradmand, Taleghani Hospital

dr.alikheradmand@yahoo.com

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

Their purpose, their relation to the instituion and the applicability

Comments