

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Therapeutic effects of low level Laser therapy in reducing anxiety, depression, and substance abuse craving in patients under methadone maintenance treatment Compared with the control group

Protocol summary

Study aim

Use of low level laser to reduce anxiety, depression and substance abuse craving in methadone maintenance patients

Design

Two arm parallel group randomized and double blinded clinical trial

Settings and conduct

In the addiction treatment clinic of Shahid Beheshti University of Medical Sciences in 1400. Patients will be randomly divided into 2 groups based on size 8 blocks. The sample size for each study group is 40 people. A total of 80 patients will be screened. Patients, data collection officers, analysts and outcome assessors will be blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients on methadone treatment who have been in treatment for at least three months Age over 18 years. Exclusion criteria: Patients treated with other methods of quitting addiction Methadone maintenance treatment less than 3 months Age under 18 years and over 60 years History of psychosis and other psychiatric disorders.

Intervention groups

The intervention group includes patients addicted to methadone treatment. This group is treated with low level light for 2 weeks and 3 sessions per week. The time of exposure to light is 4 minutes in both places of the forehead. The control group includes patients addicted to methadone treatment. In this group, the laser device is on their head but is off. They are placed under the device for 2 weeks and 3 sessions every week. Are placed. The time to stay under the device is 4 minutes in both places of the forehead.

Main outcome variables

Anxiety rate; Depression rate; Opioid craving scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210502051162N1**

Registration date: **2021-08-25, 1400/06/03**

Registration timing: **prospective**

Last update: **2021-08-25, 1400/06/03**

Update count: **0**

Registration date

2021-08-25, 1400/06/03

Registrant information

Name

Helia Helali

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2205 7254

Email address

heliahelali1990@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-06, 1400/06/15

Expected recruitment end date

2022-05-05, 1401/02/15

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 anxiety, depression, and substance abuse craving in patients under methadone maintenance treatment
Compared with the control group

Public title

Therapy with low level Laser therapy in patients under methadone maintenance treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients on methadone treatment who have been in treatment for at least three months
Age over 18 years
Admission will be regardless of gender or ethnicity

Exclusion criteria:

Patients treated with other methods of quitting addiction
Methadone maintenance treatment less than 3 months
We excluded patients who were not between the ages of 18 and 60
Anyone with a history of psychosis and other psychiatric disorders (bipolar, etc.)
A history of violent behavior, a history of moving or attempting suicide in the past

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly divided into two groups. The randomization tool used will be a table of random numbers. In order to randomize, a random block method will be used. For this purpose, we formed blocks of size 8. In each block, 4 individuals will be in intervention group and 4 will be in control group. A total of 10 blocks will be considered for the study. It will be used to blinding, similar devices without labels and only with code. In the intervention group, patients will be treated with a low level laser device, and in the control group, the device will be on their head, but it will be off.

Blinding (investigator's opinion)

Double blinded

Blinding description

Clinical caregivers and patients will be unaware and blind to the type of treatment. It will be used to hide similar devices, without labels and only with code. In the intervention group, patients will be treated with a low level light device, and in the control group, the device will be on their head, but it will be off. Patients will be

aware that they will be randomly assigned to one of the two treatment groups, but will not know which treatment will be offered in that group. Patients will be placed in one of two groups using a random number table. The clinician also knows that patients will be treated in two different ways, but will not know which method will work for each patient. The data collector, analyst and outcome assessor will collect and analyze information based on groups 1 and 2, and will not be aware of the type of treatment provided in the groups. They will be kept blind.

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

Tehran, Evin, Shahid Shahriari Square

City

Tehran

Province

Tehran

Postal code

1965715551

Approval date

2021-06-07, 1400/03/17

Ethics committee reference number

IR.SBMU.MSP.REC.1400.111

Health conditions studied

1

Description of health condition studied

Addiction

ICD-10 code

F11

ICD-10 code description

Opioid related disorders

Primary outcomes

1

Description

Anxiety rate

Timepoint

After the end of treatment and one month after the last treatment

Method of measurement

HAM-A Through a questionnaire (Hamilton Anxiety measure scale)

2

Description

Depression rate

Timepoint

After the end of treatment and one month after the last treatment

Method of measurement

HAM-D Through a questionnaire (Hamilton depression measure scale)

3

Description

opioid craving scale

Timepoint

After the end of treatment and one month after the last treatment

Method of measurement

OCS Through a questionnaire (opioid craving scale)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: This group is treated with low level Laser therapy for 2 weeks and 3 sessions per week. The time of exposure to light is 4 minutes in both places of the forehead. This treatment involves the use of a light emitting diode with a maximum wavelength of 810 nm with a full width of up to 40 nm. Creates radiation of 250 mW/cm² when applied to 4 mm of skin.

Category

Treatment - Devices

2

Description

Control group: In this group, the laser device is on their head but it is off. They are placed under the device for 2 weeks and 3 sessions every week. Are placed. The time to stay under the device is 4 minutes in both places of the forehead.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Drug abuse treatment centers in Tehran

Full name of responsible person

unknown

Street address

ran, Tehran Velenjak St. , Shahid Chamran Highway

City

Tehran

Province

Tehran

Postal code

1985711151

Phone

+98 21 2303 1111

Email

taleghanihospital@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr.Babak Shokri

Street address

Tehran Province, Tehran, District 1, Daneshjou Boulevard, 19839 69411

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Tehran

Province

Tehran

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1983969411

Phone

+98 21 29901

Fax

+98 21 2243 1607

Email

pr.office@mail.sbu.ac.ir

Web page address

<https://www.sbu.ac.ir/>

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
Helia Helali
Position
resident
Latest degree
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Other areas of specialty/work
Psychiatrics
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Person responsible for updating data

Contact

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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

No - There is not a plan to make this available

Title and more details about the data/document

Only part of the data such as information about the main outcome or the like can be shared.

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

Our data will only be available to researchers working in academia

Under which criteria data/document could be used

Any statistical analysis is allowed

From where data/document is obtainable

helia helali 09127103907 heliahelali1990@yahoo.com

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

Upon request, information will be sent via email or phone as soon as possible

Comments