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 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 under18 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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Postal code
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
Medical doctor
Other areas of specialty/work
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Person responsible for updating data

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heliahelali1990@yahoo.com

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