

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Investigating Effectiveness of Laser Acupuncture Along With Intensive Short-term Dynamic Psychotherapy on Improvement of Major Depression

Protocol summary

Study aim

Comparison of the effectiveness of laser acupuncture, Intensive short-term dynamic psychotherapy and the combination of the two mentioned treatments in improving people with major depressive symptoms with Shedler-Westen Assessment Procedure test

Design

This study is a phase 3 clinical trial. 45 patients are divided into three groups of 15 people receiving laser acupuncture treatment (group I), Intensive short-term dynamic psychotherapy (group II) a combination of laser acupuncture with Intensive short-term dynamic psychotherapy. Before, middle, end, six months after treatment, the Hamilton and Beck questionnaire is completed.

Settings and conduct

Patients with major depressive disorder referred to the New Insight Center will be randomly assigned to one of three treatment groups. Assessment will be done in four times by Hamilton and Beck psychological scales.

Participants/Inclusion and exclusion criteria

inclusion criteria: Major Depressive Disorder Patient satisfaction Exclusion criteria: Psychiatric disorders Substance or alcohol abuse Mental retardation disorders Algebraic obsessive-compulsive disorder Hypothyroidism Endocrine Disorders

Intervention groups

Laser Acupuncture (Group I); Intensive short-term dynamic psychotherapy (Group II); Combination of acupuncture laser treatments and Intensive short-term dynamic psychotherapy (group III)

Main outcome variables

Hamilton questionnaire score; Beck questionnaire score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20111121008146N37**

Registration date: **2021-12-21, 1400/09/30**

Registration timing: **retrospective**

Last update: **2021-12-21, 1400/09/30**

Update count: **0**

Registration date

2021-12-21, 1400/09/30

Registrant information

Name

Mohammadreza Razaghi

Name of organization / entity

Laser application in medical sciences research center

Country

Iran (Islamic Republic of)

Phone

+98 21 2271 8021

Email address

laser.cntr@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-21, 1397/02/01

Expected recruitment end date

2019-06-22, 1398/04/01

Actual recruitment start date

2018-09-23, 1397/07/01

Actual recruitment end date

2019-06-22, 1398/04/01

Trial completion date

2019-06-22, 1398/04/01

Scientific title

Investigating Effectiveness of Laser Acupuncture Along With Intensive Short-term Dynamic Psychotherapy on Improvement of Major Depression

Public title

Effectiveness of Laser Acupuncture on Improvement of Major Depression

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Major Depression Patient satisfaction

Exclusion criteria:

No psychiatric disorders No substance or alcohol abuse
No mental retardation No Obsessive-compulsive personality disorder No hypothyroidism No endocrine problems

Age

From **25 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **15**

Actual sample size reached: **15**

Randomization (investigator's opinion)

Randomized

Randomization description

Single-digit random numbers were generated using Excel software. The order of these random numbers was considered as the number of people entering the study. If these numbers were between 1-3, the patient was assigned to the first group, between 4-6 to the second group, between 7-9 to the third group. Following the work of each group, to which 15 patients were assigned, the generated numbers related to that group were removed from the random number production chain.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features

-

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics in Biomedical Research of Shahid Beheshti University of medical sciences

Street address

Daneshjoo Blvd, Yaman street

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2018-02-18, 1396/11/29

Ethics committee reference number

IR.SBMU.RETECH.REC.1396.1293

Health conditions studied**1****Description of health condition studied**

Major depression

ICD-10 code

6A80.2

ICD-10 code description

Current depressive episode persistent

Primary outcomes**1****Description**

Hamilton and Beck questionnaure

Timepoint

Before study-middle session of intervention-end of intervention-six months after

Method of measurement

Hamilton and Beck questionnaure

Secondary outcomes

empty

Intervention groups**1****Description**

The first group(acupuncture laser):12 sessions of stimulation of body points (LI4-LI11- ST36-ST40-BL18-BL20-BL21-SP4-SP6-LIV3-LIV8-LIV14-GB15-GB20-GB34-REN12-REN17-P6-DU20-HT7) and punctuation (Heart, pleen, Stomach, Spleen, Shenmen, Anti-depression, Valium, Master Omega) as determined by TCM diagnosis, by continuous contact gallium-aluminum-arsenide laser acupuncture (GaAlAs), with an output power of 200 mW; The wavelength is 980 nm and the dose is 4 j / point.

Category

Treatment - Devices

2**Description**

The second group(Control group):Twelve one-hour sessions of "intensive and short-term dynamic psychotherapy" focus on neutralizing defensive reactions and releasing emotions within the framework of the conflict triangle and the personal triangle.

Category

Treatment - Other

3

Description

Group 3, intensive and short-term dynamic psychotherapy and simultaneous laser acupuncture. In this way, they will first attend the laser therapy session and then the psychotherapy session on the same day.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Binesh No clinic center

Full name of responsible person

Nima Ghorbani

Street address

Unit 34, Binesh Building, No12, Kokab dead end, Pasdaran St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Afshin Zarghi, Vice chancellor of research affair, Shahid Beheshti university of medical sciences

Street address

Yaman st, Daneshjoo Blvd, Velenjak Ave

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info@sbmu.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

Arista Shojaedin

Position

Researcher

Latest degree

Medical doctor

Other areas of specialty/work

Others

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Person responsible for scientific inquiries

Contact

Name of organization / entity

laser application in medical sciences research center

Full name of responsible person

Zahra Razzaghi

Position

researcher

Latest degree

Ph.D.

Other areas of specialty/work

Biostatistics

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Person responsible for updating data

Contact

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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

There is no more information

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

No - There is not 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

Not applicable

Title and more details about the data/document

data of Laser acupuncture in the treatment of depression

When the data will become available and for how long

from 2018

To whom data/document is available

researcher

Under which criteria data/document could be used

proposal presentation

From where data/document is obtainable

laser application in medical sciences research center

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

Submit a proposal Approval the proposal Receive data

Comments

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