

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effects of photobiomodulation therapy(low level LASER therapy) on functional capacity and quality of life of patients with heart failure reduced ejection fraction who are on cardiac rehabilitation programs : (double blind randomized)

Protocol summary

Study aim

The primary objective of the present study is to show the beneficial effect of photobiomodulation therapy(PBMt) on heart failure patients

Design

A concealed, randomized, blinded, placebo controlled clinical trial with a parallel group design of 30 heart failure patients with blinded outcome assessment .(Phase 3)

Settings and conduct

We will enroll patients who have diagnosed as heart failure reduced ejection fraction for cardiac rehabilitation program. The study will be conducted in cardiac reh department of Rajaie cardiovascular medical and research center and low level LASER probe will be placed on the forearm skin at the 6 acupuncture points(PC6, PC7,HR4,HR5,HR6,ULNAR ARTERY ACUPOINT). In the placebo group the LASER system will remain off -state . Both patient and outcomes evaluator will be blinded

Participants/Inclusion and exclusion criteria

Participants: patients who have diagnosed as heart failure (a left ventricular ejection fraction equal or less than 40 %) who have been referred for cardiac rehabilitation program

Intervention groups

The patients were randomized into two groups: (1)active Low level LASER therapy group (n=15)—subjects who will be submitted to active laser therapy and (2) placebo low level LASER therapy group (n=15)—subjects who will be submitted to placebo laser after 20 minutes LASER/placebo therapy ,the patients will go for aerobic sub maximal exercise using ergo meter bike for 20 minutes (5 minutes warm up ,two 10 minutes sessions with 5 minutes rest between them ,5 minutes cool down)

Main outcome variables

New-York heart association functional class,6 minutes'

walk test distance,serum NT-pro BNP level,quality of life score,Echocardiographic variables(LVEF,left ventricular end systolic and diastolic dimentions,LV global longitudinal strain)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191207045638N1**

Registration date: **2019-12-10, 1398/09/19**

Registration timing: **registered_while_recruiting**

Last update: **2019-12-10, 1398/09/19**

Update count: **0**

Registration date

2019-12-10, 1398/09/19

Registrant information

Name

Nasim Naderi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2392 2115

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-23, 1398/06/01

Expected recruitment end date

2020-04-19, 1399/01/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effects of photobiomodulation therapy(low level LASER therapy) on functional capacity and quality of life of patients with heart failure reduced ejection fraction who are on cardiac rehabilitation programs : (double blind randomized)

Public title
photobiomodulation therapy(low level LASER therapy) in heart failure

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Expressed readiness to comply with all study procedures and availability for the duration of the study Provision of dated and signed informed consent form Age 18-65 years A diagnosis of heart failure reduced ejection fraction (LVEF $\leq$ 40%) due to ischemic or non-ischemic etiology Optimal guideline directed medical therapies including angiotensin-converting enzymeinhibitors, β -blockers, aldosterone antagonists, and diuretics for at least 3 months NewYork Heart association function class (NYHA Class) II-III
Exclusion criteria:
History of hospitalization for any cause including acute heart failure in preceding month presence Chronic renal failure or dialysis presence of chronic hepatic failure presence of neuromuscular disorders Presence of severe chronic pulmonary disease The patients who have pace maker, intracardiac defibrillator (ICD)or cardiac resynchronization therapy(CRT) psychiatric conditions inability to perform 6 minutes walk test Cardiomyopathy secondary to cancer therapy Presence of any hematologic , Rheumatologic disorder

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

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
The randomization will be performed through block randomization, and allocation secrecy will be kept by

numbered, opaque, sealed envelopes

Blinding (investigator's opinion)
Double blinded

Blinding description
The code from the drawing of the study will be given to a care provider that set the unit to either active low level LASER therapy or placebo LASER mode; thus, the study will be conducted in a double blinded placebo-controlled manner, both to the participants and to the investigator,out come assessor and data analyser

Placebo
Not used

Assignment
Parallel

Other design features
The sample volume was calculated after a pilot trial on 5 heart failure patients .The aim in the pilot study was 6 minutes walk test distance which was increased from a mean of 300 $\pm$ 48 meter to 470 $\pm$ 60 meter after low level LASER therapy .The calculated sample volume considering two mean $\pm$ SD,alpha=1% power 97% ,was about 12 patients and 15 patient was chosen for each group

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

ethic committee of science and research branch of Islamic Azad university, Tehran/Iran

Street address

Science and Research Branch,shodada Hesarak blvd, Daneshgah Square,Sattari Highway,Tehran, I.R. IRAN

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1477893855

Approval date

2018-07-08, 1397/04/17

Ethics committee reference number

IR.IAU.SRB.REC.1397.041

Health conditions studied

1

Description of health condition studied

Heart failure reduced ejection fraction

ICD-10 code

I50

ICD-10 code description

Heart failure

Primary outcomes

1

Description

New York Heart Association functional class, Physical performance (6 minutes walk test distance)

Timepoint

Before intervention and after completion of intervention

Method of measurement

1-New York heart association (NYHA) measurement :NYHA scores range from I (no symptoms of heart failure) to IV (symptoms at rest) 2- Physical performance of patients was assessed using the 6-minute walk test (6MWT) according to the protocol of Guyatt and colleagues

Secondary outcomes

1

Description

serum level of N terminal pro-brain natriuretic peptide

Timepoint

before intervention and at the intervention completion

Method of measurement

enzyme immunoassay

2

Description

Quality of life

Timepoint

before intervention and at the intervention completion

Method of measurement

Iranian quality of life questionnaire (IHF-QOL)

3

Description

Echocardiographic data: left ventricular ejection fraction, Left ventricular end diastolic and systolic dimensions, left ventricular global longitudinal strain

Timepoint

before intervention and at the intervention completion

Method of measurement

Echocardiographic machine

Intervention groups

1

Description

Intervention group: Active LASER group (n=15) The intervention group will receive low level LASER therapy (LASER device: GALALAS, 650nm, 5mW) before submaximal aerobic exercise (cycle), laser therapy is applied (150 J/cm² per point) at 6 points on forearm at acupuncture points (PC6-PC7-HR4-HR5-HR6, ulnar artery acupuncture point) for 20 minutes

Category

Treatment - Other

2

Description

Control group:) placebo low level LASER therapy group (n=15)—subjects who will be submitted to placebo laser after 20 minutes LASER/placebo therapy. In the placebo group the LASER system will remain off-state

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Rajaie cardiovascular medical and research center

Full name of responsible person

Nasim Naderi

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Sponsors / Funding sources

1

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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

Islamic Azad University

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Persons

Person responsible for general inquiries**Contact****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Homa Bahrami

Position

Post Doc student (exercise physiology)

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study ProtocolUndecided - It is not yet known if there will be a plan to
make this available**Statistical Analysis Plan**Undecided - It is not yet known if there will be a plan to
make this available**Informed Consent Form**Undecided - It is not yet known if there will be a plan to
make this available**Clinical Study Report**Undecided - It is not yet known if there will be a plan to
make this available**Analytic Code**Undecided - It is not yet known if there will be a plan to
make this available**Data Dictionary**Undecided - It is not yet known if there will be a plan to
make this available**Title and more details about the data/document**The primary and secondary outcome measures can be
shared after completion of the trial and publishing the
study results**When the data will become available and for how long**

The data will be available after completion of the trial and

publishing the study results (January 2021)

To whom data/document is available

for people working in academic institutions or people working in businesses can also apply to receive it.

Under which criteria data/document could be used

For performing the secondary studies such as systematic reviews

From where data/document is obtainable

the email address

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

The request should be sent by email and the applicant will receive the data within a month

Comments