

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Investigating the effectiveness of laser acupuncture in controlling Coronavirus disease 2019 (COVID-19) compared to common medical treatments

Protocol summary

Study aim

Evaluating the effectiveness of laser acupuncture in the treatment of patients with severe COVID-19

Design

A randomized, single-blinded clinical trial with a parallel-group design of 60 patients. Excel software will be used for randomization.

Settings and conduct

In this research, 60 hospitalized COVID-19 patients confirmed by PCR test and chest CT-scans will participate. Patients will be randomly assigned to two treatment groups. This study is single-blinded and neither the data collector nor the data analyst will be aware of the patients' group allocations and the treatments. Group 1: Patients will receive laser acupuncture treatment in addition to the current standard care for COVID-19. Laser acupuncture method: 5-10 sessions of daily laser acupuncture using GaAlAs laser (810 nm) Group 2: Patients will receive the current standard care for COVID-19.

Participants/Inclusion and exclusion criteria

COVID-19 patients with severe pneumonia, hospitalized in the ward before requiring ICU admission

Intervention groups

Group 1: Patients will receive the current standard of care for COVID-19 in addition to laser acupuncture.

Group 2: Patients will receive the current standard of care for COVID-19.

Main outcome variables

Percentage of lung involvement; IL-6 serum levels

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT2011121008146N34**

Registration date: **2021-01-24, 1399/11/05**

Registration timing: **registered_while_recruiting**

Last update: **2021-01-24, 1399/11/05**

Update count: **0**

Registration date

2021-01-24, 1399/11/05

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

2020-09-22, 1399/07/01

Expected recruitment end date

2021-03-19, 1399/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effectiveness of laser acupuncture in controlling Coronavirus disease 2019 (COVID-19) compared to common medical treatments

Public title

Investigating the effectiveness of laser acupuncture in controlling COVID-19 compared to common medical treatments

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

COVID-19 patients with severe acute pneumonia hospitalized in the ward before requiring ICU admission
Positive PCR test result
Respiratory rate ≥ 30 per minute
Oxygen saturation $\leq 93\%$
Fraction of inspired oxygen (FIO₂) ≤ 300 mmHg
Progression of lung lesions by more than 50% within 24-48 hours in the chest CT-scans
30 to 70-year-old men and women

Exclusion criteria:

A history of cancer
A history of benign tumors
Pregnancy
A history of photosensitivity

Age

From **30 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be assigned to treatment groups using random numbers generated by excel software.

Blinding (investigator's opinion)

Single blinded

Blinding description

The data collector and the data analyst are unaware of the group allocations and the treatments.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Beheshti University Ethics Committee in Biomedical Research

Street address

Shahid Beheshti University of medical sciences,

Daneshjoo Blv, Velenjak

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2020-09-01, 1399/06/11

Ethics committee reference number

IR.SBMU.RETECH.REC.1399.509

Health conditions studied

1

Description of health condition studied

COVID-19 (Coronavirus Disease 2019)

ICD-10 code

U07.1

ICD-10 code description

COVID-19, virus identified

Primary outcomes

1

Description

Percentage of lung involvement on CT-scan or chest x-ray

Timepoint

Before the intervention and after the last session of laser acupuncture treatment

Method of measurement

CT-scanner and portable x-ray unit

2

Description

IL-6 serum levels

Timepoint

Before the intervention and after the last session of laser acupuncture treatment

Method of measurement

IL-6 ELISA kit

Secondary outcomes

1

Description

Respiratory rate per minute

Timepoint

Before the intervention and after the each session of laser acupuncture treatment

Method of measurement

Counting the number of breaths in one minute

2

Description

Heart rate

Timepoint

Before the intervention and after the last session of laser acupuncture treatment

Method of measurement

Electrocardiogram

3

Description

Body temperature

Timepoint

Before the intervention and after the last session of laser acupuncture treatment

Method of measurement

Thermometer

4

Description

Oxygen saturation level

Timepoint

Before the intervention and after the last session of laser acupuncture treatment

Method of measurement

Pulse oxymeter

5

Description

Partial pressure of oxygen (PaO₂)/Fraction of inspired O₂ (FiO₂)

Timepoint

Before the intervention and after the last session of laser acupuncture treatment

Method of measurement

ABG (arterial-blood gas) test

6

Description

WBC count

Timepoint

Before the intervention and after the last session of laser acupuncture treatment

Method of measurement

Measuring the number of WBCs in the patients' blood samples

Intervention groups

1

Description

Intervention group: Current standard treatments for COVID-19 and laser acupuncture. 5-10 sessions of daily laser acupuncture using GaAlAs laser (810 nm). 5 points of the Kid-LI-SJ-Ren-Lung-Spleen-ST-BL-LIV meridians and the ear acupoints (Lung - Shenmen) will be irradiated with the following parameters respectively: 1) power: 400 mW, dose: 8 J at each acupuncture point, 2) power: 200 mW, dose: 2 J at each ear acupoint.

Category

Treatment - Other

2

Description

Current standard treatments for COVID-19

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohadaye Tajrish Hospital

Full name of responsible person

Arista Shojaeddin

Street address

Shohadaye Tajrish Hospital, Tajrish, Tehran

City

Tehran

Province

Tehran

Postal code

1989934148

Phone

+98 21 2274 9221

Email

laser.cntr@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

Next to Ayatollah Taleghani Hospital, Shahid Arabi ST. Yemen street, Shahid Chamran highway, Tehran

City

Tehran

Province

Tehran

Postal code

1989934148

Phone

+98 21 2274 9221

Email

laser.cntr@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

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 shojaeddin

Position

Physician

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

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

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Full name of responsible person

Arista Shojaeddin

Position

Physician

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Arista Shojaeddin

Position

Physician

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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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 need to publish.

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

In the article and final report

When the data will become available and for how long

at the end of study

To whom data/document is available

active researcher in laser field

Under which criteria data/document could be used

further research (acceptance of laser research center)

From where data/document is obtainable

research management of laser application in medical sciences research center Shohada-e-Tajrish medical center, Tajrish sq 021-22749221

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

first if be presented the the letter and relative proposal, and seconde acceptance of main researcher

Comments

