Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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: **IRCT20111121008146N34**
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

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Iran (Islamic Republic of)

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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 ≤ 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
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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
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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
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Person responsible for updating data

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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