Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jul 2026

Evaluating the Effect of Intravenous Laser and Comparison of Laser Treatment Effect with Red and Blue Wavelengths in the Treatment of Patients with Covid-19

Protocol summary

Study aim

Determining the efficacy of intravenous low-level laser therapy in the treatment of pneumonitis in COVID-19 patients

Design

A randomized, single-blinded clinical trial with a parallel-group design of 40 patients. Excel software will be used for randomization.

Settings and conduct

All patients are divided into three groups based on the random number table (red laser case, blue laser case and control). The assigned group of subjects is placed one after the other in dark envelopes. This envelope will be returned by the treating physician only after initial assessments have been made on each individual, and the clinical evaluator will be aware of their treatment group. Treatment procedure with low power gallium arsenide laser diode device 660 nm with an output dose of 2 joules per square centimeter, continuous for 7 minutes 5 sessions daily intravenous laser. The same dose of laser with the same time as the first group with low power laser diode with a wavelength of 450 nm is prescribed to patients in the case of blue laser. In this method, the laser light is irradiated directly into the blood through a sterile disposable catheter. Two millimeters of optical fiber enters the vein and spreads into the bloodstream. This method is just like a serum injection. The control group and cases are all treated routinely

Participants/Inclusion and exclusion criteria

Participants: COVID-19 patients with more than 50% lung involvement Exclusion criteria: Pregnancy, lactation, cardiovascular disease, hyper- and hypothyroidism, photosensitivity, a history of seizure

Intervention groups

Intervention group: Patients will receive intravenous laser treatment in addition to the current standard of care for COVID-19. Control group: Patients will receive the current standard of care for COVID-19.

Main outcome variables

Lung involvement on CT-scan, IL-6 serum levels

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20111121008146N39**
Registration date: **2022-08-02, 1401/05/11**
Registration timing: **registered_while_recruiting**

Last update: **2022-08-02, 1401/05/11**
Update count: **0**

Registration date

2022-08-02, 1401/05/11

Registrant information

Name

Mohammadreza Razaghi

Name of organization / entity

Laser application in medical sciences research center

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-23, 1400/06/01

Expected recruitment end date

2022-08-23, 1401/06/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluating the Effect of Intravenous Laser and Comparison of Laser Treatment Effect with Red and Blue Wavelengths in the Treatment of Patients with Covid-19

Public title
Evaluating the Effect of Intravenous Laser and Comparison of Laser Treatment Effect with Red and Blue Wavelengths in the Treatment of Patients with Covid-19
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Fever Cough Pneumonitis Positive PCR test Lung involvement>50% Taking any medication within the past month age between 30-80 year
Exclusion criteria:
Pregnancy Lactation Cardiovascular disease Hyper- and hypothyroidism Photosensitivity A history of seizure
Age
From **30 years** old to **80 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
The data analyst was blinded to the grouping of the data. Grouping based on the definition of codes such as A, B, C or 1, 2, and 3 will be provided to the data analyst, and the analyst does not know how to assign these codes to which treatment group.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Shahid Beheshti university of medical sciences
Street address
Daneshjo Blvd, Velenjak, Tehran, Iran
City
tehran
Province
Tehran
Postal code
1985717443
Approval date
2021-08-09, 1400/05/18
Ethics committee reference number
IR.SBMU.RETECH.REC.1400.341

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
Lung involvement on CT-scan
Timepoint
Before the intervention and after the last session of intravenous laser therapy
Method of measurement
CT-scanner

2

Description
IL-6 serum levels
Timepoint
Before the intervention and after the last session of intravenous laser therapy
Method of measurement
IL-6 ELISA kit

Secondary outcomes

1

Description
Fever
Timepoint
Before the intervention and after the last session of intravenous laser therapy
Method of measurement
Thermometer

2

Description
Oxygen saturation level
Timepoint
Before the intervention and after the last session of intravenous laser therapy
Method of measurement
Pulse oxymeter

3

Description
PO2 (partial pressure of oxygen)
Timepoint
Before the intervention and after the last session of intravenous laser therapy
Method of measurement
ABG (arterial-blood gas) test

4

Description
PCO2 (partial pressure of carbon dioxide)
Timepoint
Before the intervention and after the last session of intravenous laser therapy
Method of measurement
ABG (arterial-blood gas) test

5

Description
Respiratory rate per minute
Timepoint
Before the intervention and after the last session of intravenous laser therapy
Method of measurement
Counting the number of breaths in one minute

6

Description
WBC count
Timepoint
Before the intervention and after the last session of intravenous laser therapy
Method of measurement
Patients' blood samples

7

Description
Platelet count
Timepoint
Before the intervention and after the last session of intravenous laser therapy
Method of measurement
Patients' blood samples

8

Description
ESR (erthrocyte sedimentation rate)
Timepoint
Before the intervention and after the last session of intravenous laser therapy
Method of measurement
Patients' blood samples

9

Description
CRP (C-reactive protein)
Timepoint
Before the intervention and after the last session of intravenous laser therapy
Method of measurement
Patients' blood samples

Intervention groups

1

Description
Two case groups: The treatment procedure with a low-power gallium arsenide 660 nm laser diode with an output dose of 2 joules per square centimeter, continuous for 7 minutes 5 sessions daily under intravenous laser. The same dose of laser with equal time of the first group with low power laser diode laser with a wavelength of 450 nm is prescribed to patients in the case of blue laser
Category
Treatment - Other

2

Description
Control group: Patients will receive the current standard of care for COVID-19
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shohadaye Tajrish Hospital
Full name of responsible person
Maryam Barati
Street address
Shohadaye Tajrish Hospital, Tajrish, Tehran
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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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laser.cntr@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
Maryam Barati
Position
General Practitioner
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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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
Yes - There is a plan to make this available
Title and more details about the data/document
All data is potentially shareable after unidentified individuals
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
Researchers and doctors
Under which criteria data/document could be used
Email the corresponding author and earn permission
From where data/document is obtainable
Email the corresponding author
What processes are involved for a request to access data/document
Email the corresponding author, the authors' meeting, send the data at your discretion
Comments