

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

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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

AgeFrom **30 years** old to **80 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample sizeTarget 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

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Daneshjo Blvd, Velenjak, Tehran, Iran

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tehran

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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

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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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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

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)

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