

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

The short-term and long-term effects of laser therapy on pulmonary function and inflammatory factors in patients with COVID-19 during acute stage

Protocol summary

Study aim

The effect of laser therapy on pulmonary function and inflammatory factors in patients with Covid 19 in the acute phase of the disease

Design

A randomized controlled double-blind clinical trial with parallel groups. Phase 3 on 30 patients. A random table of numbers will be used for randomization.

Settings and conduct

This research will be conducted in Kosar Hospital of Semnan University of Medical Sciences. After enrollment in the study, patients will be randomly assigned into active and sham-laser groups and then in the intervention group, patients will be intervened with 5 sessions of high power laser. In both groups, standard treatments include non-invasive ventilation, antibiotics (oral and injectable if needed), supportive vasopressor, artificial kidney, and extracellular membrane oxygenation. In the control group, standard treatment with sham-laser will be performed on the same points.

Participants/Inclusion and exclusion criteria

Inclusion criteria included individuals with COVID-19 with a positive PCR test who will be hospitalized due to severe pulmonary involvement. Patients who inevitably undergone to use invasive ventilation or if there is a contraindication for laser treatment will also excluded from the study.

Intervention groups

The first group includes active laser in which the laser will be applied for 5 daily sessions. In the control group, exactly the same method, but when the device set is off, the probe will move. The laser protocol including C.P.S waves, will be used for 30 minutes (15 minutes on each side) at 650 and 905 nm to reduce pneumonia.

Main outcome variables

Pneumonia severity indices, and laboratory tests including O2 saturation (SaO2), inflammatory factors

including Lymph percentage, Neutrophil / Lymphocyte ratio, Interleukin-6, Ferritin, Erythrocyte sedimentation ratio, low density lipoprotein, C-Reactive protein.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160808029264N10**

Registration date: **2021-04-13, 1400/01/24**

Registration timing: **registered_while_recruiting**

Last update: **2021-04-13, 1400/01/24**

Update count: **0**

Registration date

2021-04-13, 1400/01/24

Registrant information

Name

Rasool Bagheri

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 23 3344 1022

Email address

rasool.bagheri@ymail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-03, 1400/01/14

Expected recruitment end date

2021-07-22, 1400/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The short-term and long-term effects of laser therapy on pulmonary function and inflammatory factors in patients with COVID-19 during acute stage

Public title

The effects of laser therapy in patients with COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Positive PCR test The ratio below 300 mm Hg for the pressure of oxygen (Pao2) to the inspired oxygen (Fio2) Hospitalized in the internal or special ward of the hospital Severe pulmonary involvement based on CT scan Severe stage of the disease

Exclusion criteria:

Intubation of the patient Ratio more than 300 mm Hg Mild to moderate severity of the disease Diseases such as lung and spinal cancer, heart disease, high high blood pressure and any conditions that are contraindicated for laser therapy.

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

A simple randomization method using a random number table, individuals will be randomly divided into two groups including intervention and control. Random units are each of patients infected with covid-19 that admitted to the emergency department. Also, The randomization tool is a random number table. The researcher select one of the numbers in the random numbers table and moves to the right and down. Record the numbers and assign them to different study groups whose numbers are already specified.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients will be blinded whether they are in the active or sham LASER group (the laser device will be used at the same points and for the same duration, which will be set on in the intervention group and off in the control group). In addition, the evaluator will not aware which patient assigned in two groups.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Semnan University of Medical Sciences

Street address

Basij Blvd., Semnan University of Medical Sciences.

City

Semnan

Province

Semnan

Postal code

3514799442

Approval date

2021-02-26, 1399/12/08

Ethics committee reference number

IR.SEMUMS.REC.1399.316

Health conditions studied**1****Description of health condition studied**

Respiratory infection due to COVID-19

ICD-10 code

B34.2

ICD-10 code description

Coronavirus infection, unspecified

Primary outcomes**1****Description**

Pneumonia severity indices

Timepoint

Before and after the study

Method of measurement

Pulmonary CT-scan

2**Description**

Laboratory tests

Timepoint

Before and after the study

Method of measurement

Inflammatory factors such as Interleukin-6, ferritin, C-reactive protein, Erythrocyte sedimentation rate and blood factors

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: standard treatment associated with High-power laser (lumix® 3 model manufactured by Italian physioline company) for 5 sessions every other day with C.P.S anti-inflammatory protocol and 3600 per session for 30 minutes, which is applied for 15 minutes per lung. Standard treatment Includes supplemental oxygen (if needed), non-invasive ventilation, antibiotics (oral and injectable if needed), supportive vasopressor, artificial kidney (renal-replacement therapy), and extracellular membrane oxygenation.

Category

Rehabilitation

2

Description

Control group: Standard treatment associated with the sham-laser are applied to similar points on the lungs for 30 minutes.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Kowsar Hospital

Full name of responsible person

Dr Mahbubeh Darban

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Basij Blvd., Kosar Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

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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

Semnan 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

Semnan University of Medical Sciences

Full name of responsible person

Dr Rasool Bagheri

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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

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

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - 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