

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Comparison of serum inflammatory mediators levels in patients affected by COVID-19 with and without photobiomodulation (PBM)

Protocol summary

Study aim

Assessment the changes in serum IL-1beta, IL-6, IL-8, IL-10, IL-12, TNF-alpha and TGF-beta after using red light on the skin of COVID-19 patients with pneumonia

Design

Randomized controlled trial with two parallel single-blinded groups of intervention and control each containing 21 participants who will be simply randomized. Patients with even number codes will get photobiomodulation therapy but patients will odd number codes will not. Photobiomodulation technique and its anti-inflammatory effect will be compared among the groups with COVID-19 pneumonia. Before and 3 days after using photobiomodulation, serum level of some inflammatory factors will be measured and compared. This study is at phase 2 of research.

Settings and conduct

Setting: Internal ward of Masih Daneshvari Hospital in Tehran. Blinding method: Non of the participants know whether the device is off or on disregarding their group of participation.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Pneumonia; Age>15 years; Consent to participation. Non-inclusion criteria: Intubation; Death or discharge; Dermal hypersensitivity; Psoriasis; Local inflammation at the site of using device

Intervention groups

Intervention group: Patients with COVID-19 pneumonia who get photobiomodulation. Control group: Patients with COVID-19 pneumonia who will use the photobiomodulation turned-off device at the same locations of body.

Main outcome variables

IL-1 beta; IL-6; IL-8; IL-10; IL-12; TNF-alpha; TGF-beta

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200616047799N1**

Registration date: **2020-08-23, 1399/06/02**

Registration timing: **retrospective**

Last update: **2020-08-23, 1399/06/02**

Update count: **0**

Registration date

2020-08-23, 1399/06/02

Registrant information

Name

Mehran Marashian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2712 2604

Email address

mehranmarashian@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-30, 1399/04/10

Expected recruitment end date

2020-07-31, 1399/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of serum inflammatory mediators levels in patients affected by COVID-19 with and without photobiomodulation (PBM)

Public title

Photobiomodulation anti-inflammatory effect in COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

COVID-19 Pneumonia Written consent Older than 15 years

Exclusion criteria:

Intubated patients Skin hypersensitivities or its history Psoriasis Inflammation of the site of PBM implementation

Age

From **15 years** old

Gender

Both

Phase

1-2

Groups that have been masked

- Participant

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Every patient is given a code at the first step of hospitalization. We use the last digit of the code which is odds or even to randomize the patients. This will be simple randomization for each person separately.

Blinding (investigator's opinion)

Single blinded

Blinding description

We will use turned-on device for the participants who are in the intervention group while the control group will use the turned-off device.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Masih Daneshvari Hospital

Street address

Masih Daneshvari hospital, Darabad, Niavaran

City

Tehran

Province

Tehran

Postal code

1956944413

Approval date

2020-04-19, 1399/01/31

Ethics committee reference number

IR.SBMU.NRITLD.REC.1399.131

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

COVID-19

ICD-10 code

U07.1

ICD-10 code description

COVID-19, virus identified

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

Interleukin-6

Timepoint

Immediately before intervention, 12, 24, 48, 72 hours after intervention

Method of measurement

ELISA immunologic kit (produced by R&D company)

2**Description**

IL-1-beta

Timepoint

Immediately before intervention, 12, 24, 48, 72 hours after intervention

Method of measurement

ELISA immunologic kit (produced by R&D company)

3**Description**

IL-8

Timepoint

Immediately before intervention, 12, 24, 48, 72 hours after intervention

Method of measurement

ELISA immunologic kit (produced by R&D company)

4**Description**

IL-10

Timepoint

Immediately before intervention, 12, 24, 48, 72 hours after intervention

Method of measurement

ELISA immunologic kit (produced by R&D company)

5**Description**

IL-12

Timepoint

Immediately before intervention, 12, 24, 48, 72 hours after intervention

Method of measurement

ELISA immunologic kit (produced by R&D company)

6

Description

TNF-alpha

Timepoint

Immediately before intervention, 12, 24, 48, 72 hours after intervention

Method of measurement

ELISA immunologic kit (produced by R&D company)

7

Description

TGF-beta

Timepoint

Immediately before intervention, 12, 24, 48, 72 hours after intervention

Method of measurement

ELISA immunologic kit (produced by R&D company)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Photobiomodulation with red light on patients' chest , back and neck for 3 days each day for 15 minutes. The device named "Neolys" manufactured by "Life+" company in France.

Category

Treatment - Devices

2

Description

Control group: The device is used for the intervention body location every day for 3 days each for 15 minutes but the device will not be turned-on.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Masih Daneshvari Hospital

Full name of responsible person

Mehran Marashian

Street address

Masih Daneshvari hospital; Darabad avenue; Bahonar street

City

Tehran

Province

Tehran

Postal code

1995657485

Phone

+98 21 2712 2604

Email

mehranmarashian@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Research department

Street address

Masih Daneshvari hospital; Darabad; Bahonar street

City

Tehran

Province

Tehran

Postal code

1996758465

Phone

+98 21 2712 2604

Email

mehranmarashian@gmail.com

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

Mehran Marashian

Position

Researcher

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner
Street address
Masih Daneshvari hospital; Darabad; Bahonar street
City
Tehran
Province
Tehran
Postal code
Tehran
Phone
+98 21 2712 2604
Email
mehranmarashian@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Alireza Eslaminejad
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
Street address
Masih Daneshvari hospital; Darabad; Bahonar street
City
Tehran
Province
Tehran
Postal code
Tehran
Phone
+98 21 2712 2604
Email
mehranmarashian@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mehran Marashian
Position
researcher
Latest degree
Medical doctor
Other areas of specialty/work

General Practitioner
Street address
Masih Daneshvari hospital; Darabad; Bahonar street
City
Tehran
Province
Tehran
Postal code
Tehran
Phone
+98 21 2712 2604
Fax
+98 21 2610 9647
Email
mehranmarashian@gmail.com

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

No - There is not 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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Data set will be very hardly shared if necessary and in specific condition.

When the data will become available and for how long

Immediately after publishing all the planned articles.

To whom data/document is available

Related researchers who necessarily need the data will be gave them.

Under which criteria data/document could be used

Research ethics and research rights have to be considered in this regard.

From where data/document is obtainable

The affiliations of the authors would be available when the articles published.

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

The corresponding author would be available by email and will explain the prerequisites and time to give the data.

Comments