Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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)

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+98 21 2712 2604

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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

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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

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Tehran

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1996758465

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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

Mehran Marashian

Position

Researcher

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Masih Daneshvari hospital; Darabad; Bahonar street

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Alireza Eslaminejad

Position
Assistant Professor

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Subspecialist

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Internal Medicine

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researcher

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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
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