

# Anti-viral photodynamic therapy in COVID-19 management: a novel approach in treating patients in early infection stages

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| <b>Submission date</b><br>27/04/2021   | <b>Recruitment status</b><br>No longer recruiting        | <input type="checkbox"/> Prospectively registered    |
| <b>Registration date</b><br>29/04/2021 | <b>Overall study status</b><br>Completed                 | <input type="checkbox"/> Protocol                    |
| <b>Last Edited</b><br>29/04/2021       | <b>Condition category</b><br>Infections and Infestations | <input type="checkbox"/> Statistical analysis plan   |
|  |  | <input type="checkbox"/> Results                     |
|  |  | <input type="checkbox"/> Individual participant data |
|  |  | <input type="checkbox"/> Record updated in last year |

## Plain English summary of protocol

### Background and study aims

COVID-19 is a condition caused by the coronavirus (called SARS-CoV-2) that was first identified in late 2019. This virus can infect the respiratory (breathing) system. Some people do not have symptoms but can carry the virus and pass it on to others. People who have developed the condition may develop a fever and/or a continuous cough among other symptoms. This can develop into pneumonia. Pneumonia is a chest infection where the small air pockets of the lungs, called alveoli, fill with liquid and make it more difficult to breathe.

After a temporary slowdown in summer 2020 infection numbers and death rates have been increasing again in recent months leading to various restrictions of social and economic life in many countries. The latest developments of new vaccinations seem to be promising; however, large-scale production and worldwide distribution logistics take time while questions such as longevity of immune protection, long-term side-effects etc are remaining unclear at this point. Furthermore, vaccination is a preventive approach and not a treatment for acutely infected patients. Treatments are still needed to help people with COVID-19 infection. The aim of this study is to find out whether photodynamic therapy (PDT) with riboflavin and a specially designed light treatment kit would be able to fill this gap by helping people in the early stages of infection. This may lead to relief for hospitals and intensive care stations.

### Who can participate?

Acutely infected COVID-19 patients aged 10-90 from Gandhi hospital in Tehran

### What does the study involve?

Participants are randomly allocated to receive either photodynamic therapy plus daily testing for 5 days or to receive conventional care plus testing. Viral load is measured at the start of the study and after 24, 48, 72, 96, 120 and 168 hours.

### What are the possible benefits and risks of participating?

Possible benefits are lowering the viral load and improving the symptoms of Covid-19 patients. There are no significant risks or side effects to be expected according to safety measurements that have been done before.

Where is the study run from?  
Gandhi Hospital (Iran)

When is the study starting and how long is it expected to run for?  
September 2020 to February 2021

Who is funding the study?  
Weber Medical (Germany)

Who is the main contact?  
Dr. med. Michael Weber  
robert.weber@webermedical.com

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
Covid2021001

## Study information

**Scientific Title**  
Successful reduction of SARS-CoV-2 viral load by photodynamic therapy verified by quantitative PCR – a novel approach in treating patients in early infection stages

**Study objectives**  
The objective of this study is to evaluate if Photodynamic Therapy (PDT) with riboflavin and a specially designed light treatment kit would be able to help people in the early stages of infection by reducing viral load and clinical symptoms.

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**

No ethical approval required because of the emergency COVID-19 situation in Tehran/Iran in November 2020

## **Study design**

Interventional non-randomized study

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

COVID-19 (SARS-CoV-2 infection)

## **Interventions**

Patients are assigned in the sequence of hospital admission to two groups with 70 patients in the experiment (verum) group receiving daily Photodynamic Therapy and daily testing for 5 days and a control group receiving conventional care plus testing for 5 days. All patients in both groups had positive COVID-19 test results at the beginning of the study. They were in an early infection stage with mild symptoms like fever, dry cough, headache, hard breathing, fatigue etc. Quantitative PCR (QPCR) tests with Ct-viral load are performed on day 1, 2, 3, 4, 5 and 7 in the experiment group and on day 1, 3, 5 and 7 in the control group.

## **Intervention Type**

Mixed

## **Primary outcome(s)**

Viral load measured using the QPCR test (Ct value) at baseline, 24 hours, 48 hours, 72 hours, 96 hours, 120 hours and 168 hours

## **Key secondary outcome(s)**

Clinical symptoms measured using the visual analogue score (VAS) at baseline, 24 hours, 48 hours, 72 hours, 96 hours, 120 hours and 168 hours

## **Completion date**

28/02/2021

## **Eligibility**

### **Key inclusion criteria**

1. Men and women
2. Aged 10-90 years
3. Early stages of COVID-19 (SARS-CoV-2 infection)

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

**Age group**

Mixed

**Sex**

All

**Total final enrolment**

140

**Key exclusion criteria**

1. Late infection stages
2. Pregnant women
3. Children aged under 10 years

**Date of first enrolment**

01/11/2020

**Date of final enrolment**

15/02/2021

**Locations****Countries of recruitment**

Iran

**Study participating centre****Gandhi Hospital**

Gandhi St, No. 130

Tehran

Iran

1000

**Sponsor information****Organisation**

International Society for Medical Laser Applications

**Funder(s)****Funder type**

Industry

**Funder Name**

Weber Medical

**Results and Publications****Individual participant data (IPD) sharing plan**

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

**IPD sharing plan summary**

Other