ISRCTN10839729 https://doi.org/10.1186/ISRCTN10839729

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

Submission date
27/04/2021

Recruitment status
No longer recruiting

Registration date
29/04/2021

Overall study status
Completed

Last Edited
29/04/2021

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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

Contact name
Dr Michael Weber

Contact details
Sohnreystrasse 4
Lauenfoerde
Germany
37697
+49 (0)5273367780
robert.weber@webermedical.com

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

Primary study design
Interventional

Study design
Interventional non-randomized study

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