ISRCTN96796566 https://doi.org/10.1186/ISRCTN96796566

Electrical stimulation for lung muscle rehabilitation in patients with COVID-19

Submission date
10/09/2021

Recruitment status
No longer recruiting

Registration date
21/10/2021

Overall study status
Completed

Last Edited
31/03/2022

Condition category
Respiratory

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Approximately 15% of patients with SARS-CoV-2 (COVID-19) infection develop acute interstitial pneumonia which requires hospitalization and oxygen administration. Complications in severe cases of COVID-19 include acute respiratory distress syndrome (ARDS). Research results confirm that older age and D-dimer concentrations> 1 μg/L on admission to hospital are associated with higher mortality.
Currently, there are no clear guidelines on how to conduct pulmonary rehabilitation in patients with COVID-19. Studies conducted in recent years have shown that the use of physical training in patients with chronic interstitial lung diseases is safe and brings numerous benefits like improved the quality of life, physical efficiency and lowered levels of pro-inflammatory cytokines. On the other hand, prolonged inactivity leads to skeletal muscle atrophy, exercise intolerance, venous thrombosis, pulmonary embolism and pressure ulcers.
But what if a COVID-19 patient is unable to exercise due to experiencing discomfort from shortness of breath and dyspnoea?
It seems that an alternative to physical training may be neuromuscular electrostimulation (NMES) of the skeletal muscles of the lower extremities. NMES is a safe form of skeletal muscle training. It can be used in patients with moderate to severe dyspnoea in COPD, and even in patients undergoing respiratory therapy. Lower limb musle electrostimulation increases the muscle strength, improves physical performance and quality of life.
From the above argumentation, it seems justified to undertake research aimed at assessing the use of electrostimulation of the skeletal muscles of the lower extremities in the rehabilitation of patients with COVID-19.

Who can participate?
Adults suffering from COVID-19 interstitial pneumonia.

What does the study involve?
The patients will be divided into 2 comparative groups – one experimental group and one control group. Patients in the experimental group will receive NMES electrical stimulation in addition to the standard treatment. Patients in control groups will receive standard treatment according to current medical guidelines.

What are the possible benefits and risks of participating?
NMES in combination with the conventional COVID-19 treatment will contribute to a better improvement in the physical performance and quality of life of COVID-19 patients. NMES in patients with COVID-19 will result in a greater reduction in inflammation.
Possible risks are allergic reactions to the electrodes, muscle pain or paraesthesia and damage to the skin by electrodes.

Where is the study run from?
Academy of Physical Education in Katowice (Poland).
St. Elizabeths Hospital in Katowice (Poland).

When is the study starting and how long is it expected to run for?
November 2020 to January 2022

Who is funding the study?
The Academy of Physical Education in Katowice (Poland).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number

Nil known

Study information

Scientific Title
Neuromuscular electrostimulation (NMES) of skeletal muscles in the rehabilitation of patients with COVID-19 interstitial pneumonia

Study objectives
When a patient with COVID-19 is unable to exercise due to the perceived discomfort of shortness of breath, an alternative to physical training may be neuromuscular electrostimulation (NMES) of the skeletal muscles of the lower extremities.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/12/2020, Bioethics Commission for Scientific Research at The Jerzy Kukuczka Academy of Physical Education in Katowice (Mikołowska 72a Street, 40-065 Katowice, Poland; +48 (0)322075152; komisjabioetyczna@awf.katowice.pl), ref: 4/2020

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
COVID-19 interstitial pneumonia

Interventions
The study will include patients with COVID-19 interstitial pneumonia documented with positive SARS-CoV-2 RT-PCR test result.
Single-center interventional randomized controlled trial.

The intervention will consist of 2 stages.
In the first stage, after tests completion (chest CT scan, gasometry measured with the SpO2 pulse oximeter, ECG, anthropometric indicators and laboratory tests) and meeting the inclusion criteria, patients will be qualified by the attending physician to participate in the experiment.

In the second stage, COVID-19 patients will be randomly assigned to one of two groups:

1/ In the first group NMES electrical stimulation will be conducted in 20 COVID-19 patients in addition to the standard treatment.
Quality of life will be tested with the Polish version of the CAT questionnaire. Each patient will be assessed also using the The MRC dyspnoea scale. The exercise tolerance and dyspnoea will be assessed according to the Borg scale.

Physical capacity will be assessed by selected ADL activities (e.g. sitting alone in bed with legs lowered, lifting both lower limbs separately at 30° and holding them in this position until tired, standing alone by bed, getting out of bed and sitting alone in a chair while standing by the bed, walking without help).The implementation of the above interventions will depend on the clinical condition of the patient and will be ordered by the attending physician.
Muscle electrostimulation (NMES) will be performed 5 times a week for 40 minutes under the supervision of a physiotherapist and will last for 3 weeks (15 sessions). NMES will be conducted on thigh muscles (20 mins) and calf muscles (20 mins) of both limbs. The electrodes will be placed on the proximal and distal ends of the muscle bellies. An biphasic symmetrical electrical current of 35 Hz frequency will be used. The pulse duration will be 0.3 ms. The intensity will be set up to achieve tetanic muscle contraction with 30-45% of the maximum muscle strength. The duration of the series of pulses (duration of contraction) will be 2 seconds and the duration of the pause between series of pulses (duration of the contraction) will be 4 seconds.
Neuromuscular electrostimulation of the skeletal muscles of the lower extremities will be performed with a portable dual-circuit electrotherapy device by Mettler Electronics Trio Stimulator. Square self-adhesive electrodes with dimensions of 5cm × 5cm will be used.

2/ The second group (control) will consist of 20 COVID-19 patients treated with the current medical guidelines.
After 15 days of hospitalization, anthropometric indices (body weight, BMI, adipose tissue mass) will be determined for each patient and a CT scan of the chest and gasometry (while resting) will be performed. 10 ml of blood will be taken from each of the examined patients to determine selected laboratory parameters such as morphology, ALAT, AST, CPK, and concentrations of CRP, TNF and sTNFR, IL-6, IL-10, fibrinogen and d-dimers). Quality of life will be tested with the Polish version of the CAT questionnaire. The exercise tolerance and dyspnoea will be assessed according to the Borg scale.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Electrotherapy device Trio Stim from Mettler Electronics

Primary outcome(s)
Quality of life in COVID-19 patients assessed with the Polish version of the CAT questionnaire at baseline and after treatment.

Key secondary outcome(s))
1. Selected respiratory (gasometric) indicators measured by SpO2 pulse oximeter at baseline and after treatment.
2. Laboratory indicators (TNF, sTNFR1, IL-6, IL-10, d-dimers, CRP) measured by laboratory blood tests at baseline and after treatment.

Completion date
30/01/2022

Eligibility

Key inclusion criteria
1. COVID-19 (positive RT-PCR test and interstitial pneumonia observed in CT scan),
2. Clinically severe interstitial pneumonia with respiratory failure / pre ARDS (MEWS classification of 3-4 points),
3. <90-92% SpO2 at rest
4. Consent to participate in the study.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Unstable ischemic heart disease,
2. Significant haemodynamic aortic stenosis,
3. Valve defects requiring surgical correction,
4. Complex ventricular arrhythmias,
5. Implantation of a cardiac pacemaker, cardioverter-defibrillator (ICD) and cardiac re-synchronizing pacemaker (CRT),
6. Acute myocarditis or pericarditis,
7. Uncontrolled hypertension,
8. End-stage renal disease and liver failure disease,
9. Lack of consent to participate in the study.

Date of first enrolment
25/10/2021

Date of final enrolment
16/01/2022

Locations

Countries of recruitment
Poland

Study participating centre
The Jerzy Kukuczka Academy of Physical Education in Katowice
72a Mikołowska Street
Katowice
Poland
40-065

Study participating centre
St. Elizabeths Hospital in Katowice
52 Warszawska Street
Katowice
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40-008

Sponsor information

Organisation
Akademii Wychowania Fizycznego im. Jerzego Kukuczki w Katowicach

ROR
https://ror.org/05wtrdx73

Funder(s)

Funder type
University/education

Funder Name
Akademia Wychowania Fizycznego im. Jerzego Kukuczki w Katowicach

Alternative Name(s)
The Jerzy Kukuczka Academy of Physical Education in Katowice, AWF Katowice

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Poland

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes