Study protocol

Visualisation of changes in regional ventilation in dyspnoeic post-COVID patients
-
Case-control study using electrical impedance tomography

ViReVentPoCov

Case control study

Study acronym:	Visual reg Vent post-COVID
Protocol version:	Draft version of 19.05.2022/ Final version from 20.05.2022
Confidentiality Notice:	The contents of the present study protocol are to be treated confidentially and may not be passed on to uninvolved persons, either orally or in writing, without the consent of the study director.

1. General information

1.1 Persons, institutions and bodies involved

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Deputies of the Director of Studies or members of the Directorate of Studies *Priv.-Doz. Dr. med. habil. Philipp Reuken* *Clinic for Internal Medicine IV* *Am Klinikum 1, 07747 Jena* *Tel.:* *03641 9 - 32 4504* *E-Mail:* *phillipp. reuken@med.uni-jena.de*	**Monitoring** -
Protocol Committee -	**Data management** *Dr Jan-Christoph Lewejohann*
Study coordination/project management *Dr.. Jan-Christoph Lewejohann*	**Laboratory/s** -
Reference institutes -	

1.2 Summary

Some patients continue to suffer physical or psychological impairments weeks and months after infection with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Shortness of breath is one of the most frequently observed symptoms (15-61%), either singly or in combination (1, 2). When treating patients with dyspnoea, conventional diagnostic tools (computed tomography, spirometry, body plethysmography) often fail to detect pathological changes, making it difficult for the treating physician to choose an appropriate therapeutic approach (3-6). Therefore, it would be desirable to have an examination procedure that reveals the pulmonary changes in post-Covid patients that are hidden from other diagnostic procedures.

Electrical impedance tomography (EIT) is a non-invasive and radiation-free imaging technique that can show regional ventilation of the lungs almost "in real time" based on changes in the electrical impedance of the thorax during inspiration and expiration. This method is based on the observation that the electrical conductivities of biological tissues differ significantly depending on their nature and functional state. Clinical questions in which the inhomogeneity of lung ventilation is to be analysed (e.g. under- or overinflation of individual lung areas, lung collapse, etc.) can be investigated particularly well with EIT, since intrathoracic impedance changes correlate strongly with changes in regional lung gen ventilation (7, 8).

So far, EIT has mainly been used as a monitoring method in intensive care medicine to adapt ventilation settings and other therapeutic measures individually to the needs of the patient. In this field, the method has proven useful to get an overview of the distribution of a respiratory volume in a transverse EIT layer, to compare different lung regions, to identify inhomogeneities and to evaluate regional ventilation during spontaneous breathing.

In this retrospective case-control study, EIT data obtained during routine examinations of post-COVID patients will be used to analyse whether EIT is suitable as a radiation-free, non-invasive imaging method for assessing regional ventilation of the lungs in spontaneously breathing post-COVID patients and whether additional indications of regional ventilation disorders in these patients can be found by assessing lung ventilation by means of EIT. Since there are no reference data from spontaneously breathing lung-healthy patients so far, a reference group will be generated whose EIT data will be compared with those of the post-COVID patients.

References:

1 Fernandez-de-Las-Penas C, Palacios-Cena D, Gomez-Mayordomo V, Palacios-Cena M, Rodri guez-Jimenez J, de-la-Llave-Rincon AI, et al. Fatigue and Dyspnoea as Main Persistent Post-COVID-19 Symptoms in Previously Hospitalized Patients: Related Functional Limitations and Disability. Respi ration. 2022;101(2):132-41. PubMed PMID: 34569550. Pubmed Central PMCID: PMC8678253. Epub 2021/09/28.

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8 Gong B, Krueger-Ziolek S, Moeller K, Schullcke B, Zhao Z. Electrical impedance tomography: func tional lung imaging on its way to clinical practice? Expert Rev Respir Med. 2015;9(6):721-37. PubMed PMID: 26488464. Epub 2015/10/22.

1.3 Synopsis

Title of the study	Visualisation of changes in regional ventilation in dyspnoeic post-COVID patients - a case-control study using electrical impedance tomography
Acronym	ViReVentPoCov
Director of Studies	Dr. med. J.-C. Lewejohann
Deputy of the Director of Studies	Priv.-Doz. Dr. med. habil. Dr. P. Reuken
Indication/target population/disease	Post-COVID patients and reference group of lung-healthy subjects
Study design/methodology	- monocentric - not controlled; type and number of control groups: 1 - Case-control study (retrospective patient data from routine treatment vs. reference group)
Aims of the clinical trial/objectives	Primary objective: Examine whether post-COVID patients with dyspnoea show changes in regional ventilation compared to a reference group of lung-healthy subjects. Secondary objectives: To review the indication of EIT in post-COVID patients with dyspnoea.
Study objective	Primary target figure/main target criterion: There is a difference in regional ventilation between healthy lung patients and post-COVID patients with dyspnoea. Changes in the configuration of the minute image and the regional ventilation delay (RVD) image, the RVD diagram and video-based analysis of the dynamic images Secondary target variables/ secondary target criteria: Review of the indication for an EIT examination in patients with post-COVID syndrome
Number of patients	Number in analysis: n=20 post-COVID patients / n=80 healthy lung patients Considering the first comparison of EIT data of post-COVID patients with those of a reference group, no formal calculation of the number of patients is calculated and a patient number of n=20 and a subject number of n=80 are assumed to be sufficient. The number of subjects is planned to be higher than the number of patients so that enough reference values of EIT in the different age groups can be analysed and compared with those of the patients in the age-adjusted comparison.
Inclusion criteria	EIT data of post-COVID patients with dyspnoea from the post-COVID outpatient clinic of university hospital Jena (retrospective) and lung-healthy non-smokers without resting or exertional dyspnoea (both groups breathing spontaneously).
Exclusion criteria	- Pacemaker - BMI over 50, here the PulmoVista® 500 system should not be used according to the manufacturer. - uncontrolled body movements
Timetable (duration of study)	patient-related: Duration of study-related measures: 10 min. EIT examination Follow-up period: None study-related: Start (time): After ethics vote Recruitment period: approx. 1 week Total duration: approx. 2 weeks expected completion including evaluation (date): 15.06.2022 End of study: *after inclusion of n=20 subjects in the* reference group and evaluation of the EIT data of the post-COVID patients ten

1.4 Flowchart

Recruitment of lung-healthy subjects

↓

EIT examination of healthy lungs (n=80)
Non-invasive, radiation-free, duration 10 min.

↓

Comparison

(Retrospectively) post-COVID patients with dyspnoea

versus

lung healthy volunteers

Parameters of regional ventilation from the EIT examination
(areated regions, distribution of ventilation, non-ventilated areas, minute images, dynamic images, regional ventilation delay (RVD), pendulum air)

1.5 Visit plan

Table or list with visits and the (study-specific) events that take place, e.g. examinations and measures

Medical history/baseline data collection	+					
Informed consent	+					
Inclusion and exclusion criteria	+					
Randomisation	-					
physical examination	-					
Recording of concomitant medication	+					
Sampling for laboratory [1]	-					
Recording of adverse events	+					

1. Question or background

- conventional diagnostic tools (computed tomography, spirometry, body plethysmography) often fail to detect pathological changes in post-COVID patients with dyspnoea, which makes it difficult for the treating physician to choose an appropriate therapeutic approach
- Post-COVID patients who underwent electroimpedance tomography as part of routine diagnostics have shown clear abnormalities.
- Up to now, there are no reference data from electroimpedance tomography (areated regions, distribution of ventilation, non-ventilated areas, minute images, dynamic images, video-based analysis of dynamic images, regional ventilation delay, pendulum air) in spontaneously breathing lung patients, but only EIT data from ventilated patients and non-invasively ventilated subjects. Thus, a reference group is missing.

1.1 Initial situation

1.2 Question and justification of the project

This study aims to answer the following question:
Do spontaneously breathing post-COVID patients have changes in their regional ventilation that cannot be detected in lung-healthy subjects?

2.3 Justification of the treatment and examination procedures

Electroimpedance tomography (EIT) is a non-invasive, radiation-free imaging examination procedure based on the measurement of impedance changes. EIT can be used to visualise regional ventilation based on the electrical conductivity of the thorax at the bedside. This method therefore provides valuable information about the regional ventilation of the lungs.

3. Study objectives

- Aims of the study:
  Visualisation of regional ventilation disorders in post-COVID patients compared to a reference group.
- The study will investigate whether there are significant differences between regional ventilation (areated regions, distribution of ventilation, non-ventilated areas, minute images, dynamic images, video-based analysis of dynamic images, regional ventilation delay, pendulum air) in post-COVID patients compared to a reference group of lung-healthy subjects.

3.1 Primary study objective and primary endpoint

- Main question:
  Are there significant differences between regional ventilation in post-COVID patients compared to a reference group?
- primary endpoint (target variables):

  Relative distribution of the respiratory volume across the so-called regions of interest (ROIs). adjustable in size and arrangement, in which the ventilation ratios represented by the EITcan be measured (regional ventilation of the lung (regional ventilation of the lung: areated regions, distribution of ventilation, non ventilatedareas, minute images, dynamic images, video-based analysis of dynamic images, regional ventilation delay, pendulum air**)**

3.2 Secondary study objectives and secondary endpoints

- Side issues: none
- No secondary objective criteria

4. study design and description

4.1 Nature of the study

This is a case-control study

4.2 Type of therapy assignment

none

4.3 Number and type of comparison groups

A reference group is formed (up to now there are no published data on the target values of spontaneously breathing lung patients mentioned under 3.1).

4.4 Scope of the study

n=20 post-COVID patients, n=80 lung healthy volunteers

4.5 Patient recruitment

- Accessibility of the intended number of patients:
- Given by retrospective analysis of EIT data of post-COVID patients from the UKJ outpatient clinic (planned n=20).
- Number of participants: n=80 subjects
- Procedure for recruiting examination candidates: Addressing UKJ staff/students

4.6 Schedule

The expected total study duration is 3 months.

- Duration of the study in the individual patient: 10 minutes
- No interim evaluation planned
- End of study (end of study): after inclusion of n=80 patients in the reference group.
- If necessary, define times at which checks are carried out,
    - whether recruitment is proper: one week after the start of the study
    - Whether patient safety is ensured: not applicable, as radiation-free non-invasive procedure without known side effects.
    - whether the data quality is sufficient: before each EIT measurement by automatic calibration of the device
- possible representation of some milestones over time (indicate month/year):
    - Inclusion of first patient/proband (FPFV) June 2022
    - Inclusion of last patient/proband September 2022
    - End of study of the last patient (LPLV) -
    - Closing the database: after reaching n=80 subjects
    - End of statistical evaluation: September 2022
    - Final report: September 2022

5. required equipment

- Existing equipment and furnishings:
  2 EIT units, single examination room in the ZNA.
- required qualifications or experience of the examiners:
  Doctor; trained in EIT derivation technique
- Minimum number of subjects and patients to be included:
  n=20 subjects undergoing EIT examination;
  n=20 patients from the post-COVID outpatient clinic in whom the examination was performed as part of routine examinations (retrospective evaluation).
- Participating examiners: Dr. J.-C. Lewejohann
- an evaluation and initiation visit can be dispensed with, because the method is used in the routine
- study-specific quality requirements for diagnostic measures:
  The quality of the EIT derivation is ensured by automatic calibration at the beginning of each examination. examination. If the calibration is not passed, the examination is not possible. possible.

5.1 Conditions for participation in the study

Only adult participants who give written informed consent to participate (subjects) will be included in the study.

Lung-healthy subjects (reference group): Non-smokers, no resting or exertional dyspnoea

Post-COVID patients: presentation at the post-COVID outpatient clinic of the UKJ with subsequent EIT examination (retrospective evaluation of EIT data collected during routine diagnostics).

6. selection of patients

- *Main selection criterion: patients with a post-COVID syndrome who presented at the post-COVID outpatient clinic and lung-healthy subjects who do not smoke.*
  (retrospective analysis of EIT data of post-COVID patients examined in the post-COVID outpatient clinic of the UKJ and EIT examination of lung-healthy spontaneously breathing subjects from whose EIT data a reference group is to be formed, which does not yet exist).
- *Female and male patients can be included.*

6.1 Inclusion criteria

- *Reference group: no resting or exertional dyspnoea, non-smokers*
- *Post-COVID patients: EIT examination performed as part of routine presentation at the post-COVID outpatient clinic.*

6.2 Exclusion criteria

- Pacemaker wearers
- BMI over 50, here the PulmoVista® 500 system should not be used according to the manufacturer
- uncontrolled body movements

7. Process of the study

- Recruitment of lung-healthy subjects (UKJ staff/students)
- Formation of the reference group: for each subject, conduct an EIT examination in a quiet and distraction-free environment (single room ZNA) to avoid artefacts.
- Post-COVID patients: retrospective analysis of EIT data
- Comparison of the EIT parameters of the two groups

7.1 Description of the individual phases of the study process

7.1.1 Information and consent

- Each subject is informed about the nature, significance, objectives, possible risks, expected benefits, implications and other aspects of the study through a discussion between the investigator and the subject. The subject receives written information about the EIT study. The investigator makes sure that the subject has understood the information. After the clarification, each subject is given enough time and opportunity to clarify open questions and to decide on his or her participation.
- Each subject signs and dates his or her consent to participate in the study in writing on the consent form. The consent also explicitly refers to the collection and processing of personal data. Therefore, the subjects are explicitly informed about the purpose and scope of the collection and the use of these data, especially health data.
- One copy of the signed consent form (copy or 2nd original) is given to the subject, the other remains at the trial centre.
- The proband may withdraw consent and discontinue the examination or terminate the study at any time and without giving reasons. In such cases, the proband is asked to state the reason for discontinuation (for the treatment or participation), but is advised that he/she does not have to do so. The time of withdrawal of consent to treatment or study shall be documented.
- Information and consent about planned publication of data

7.1.2 Randomisation

- not applicable

7.1.3 Treatment phase

- not applicable

7.1.4 Examinations in the context of discharge

- not applicable

7.1.5 Follow-up examinations

- not applicable

7.2 Description of the individual visits

- not applicable

7.3 Description of laboratory and other examinations and methods

EIT is a radiation-free non-invasive imaging procedure that provides a special view into the lungs. In a cross-sectional projection, the distribution of the respiratory volume in the thorax is displayed.

In this representation, ventilated and non-ventilated areas of the lung can be seen, as well as their changes depending on time.

7.4 End of study participation

The regular end of study participation for each participant: Completion of the EIT investigation.

7.4.1 Premature withdrawal of a patient from the study (discontinuation criteria)

Participation in the EIT investigation is voluntary. Each participant has the right to withdraw from the study prematurely at any time at his or her own request and without giving reasons (consent is withdrawn) or to decide to discontinue the study (no further EIT study) without incurring any disadvantages.

Should a participant withdraw consent and drop out of the study, this constitutes a discontinuation of participation. The participant is asked to state the reason for dropping out, but is advised that they do not have to do so. It will be documented that, when and, if applicable, why he/she withdrew his/her consent.

7.4.2 Procedure after (early) departure

Deleting the EIT data on the machine

7.5 End of the study

7.5.1 Regular end of studies

The study participation ends regularly for each study participant after completion of the EIT examination.

7.5.2 Early study end/termination of the entire study

Possible reasons for premature termination of the entire study are:

- Inadequate recruitment rate

The decision to discontinue the study is made by the study director and his/her deputy.

8. adverse events

8. 1 Possible complications and/or risks

- Side effects known so far: none known and published so far,

  pressure points on the skin are possible due to the EIT belt, because the examination is performed lying down with the upper body elevated by 30°.
- study-specific complications:

  None to be expected, as non-invasive and radiation-free examination

  In all studies published so far on EIT, especially in the field of intensive care, no complications have been described.
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8.2 Recording and documenting adverse events

- none are to be expected, as none have been described in the literature so far and are not to be expected by the nature of the investigation.

9. biometrics

9.1 Endpoints

9.3 Planning the scope of the study (caseload planning)

Considering the first comparison of EIT data of spontaneously breathing lung-healthy subjects compared to patients with dyspnoea in the context of a post-COVID syndrome, a subject number of n=80 and patient number of n=20 each is assumed to be sufficient for the investigation of significant differences. The number of subjects is planned to be higher than the number of patients so that enough reference values of EIT in the different age groups can be analysed and compared with those of the patients in the age-adjusted comparison.

9.4 Statistical evaluation

The comparison of the 32x32 pixel matrices of the EIT images [tidal images] and the comparison of the relative distribution of the breath volume across the ROIs is done with the Wilcoxon rank sum test.

9.5 Interim evaluation(s)

- none planned

10. data management

10.1 Patient identification list

All patient-related data is recorded in pseudonymised form. For this purpose, a non-speaking pseudonym is used, from which alone the identity of the patient cannot be inferred. In order to obtain unique patient identification numbers, a combination of a fixed trial centre number and a consecutive centre-specific patient number is chosen.
The trial centre maintains a patient identification list in which the patient identification numbers are linked to the full patient names of the participants, patient identification number and date of birth, if applicable. This list serves the possibility of later identification of participating persons. It will be kept absolutely confidential and will not leave the trial centre. It will be archived for **at least ten years** after the end of the study.

10.2 List of responsibilities

A signature list with the name, function in the study, study-related activity and abbreviations of the responsible persons is filed in the study centre folder.

10.3 Data collection/documentation forms

To achieve the study objective, it is necessary to collect and process medical data from individual patients. Data collection takes place at the trial centre involved in the study. The data collection is paper-based.

10.4 Data processing

- takes place pseudonymised in Excel, SPPS and MatLAB

10.6 Study documents and their storage (archiving)

The originals of all essential study documents shall be retained by the study director for at least ten years after the preparation of the final report.
At the trial centre, the accrued administrative documents (e.g. correspondence with ethics committee(s), study management), the patient identification list, the signed consent forms and the general study documentation (study protocol, amendments) are stored for the above-mentioned period. All documentation will be kept securely and treated confidentially. The patient identification list will be kept separately from the documentation records.
Original study patient data (e.g. medical records) or essential study documents shall be retained in accordance with the archiving period applicable to the trial sites, but not less than ten years). The trial site or the responsible person shall take precautions to prevent the accidental or premature destruction of these documents.

10.7 Data protection

Within the framework of the study, it is necessary to collect and process personal data from the study participants (e.g. full name, initials of first and last name, date of birth, address) and data on the course of the disease (e.g. medical findings, types of treatment, prescribed medication). These data are collected at the trial centre and stored electronically in pseudonymised form (i.e. without direct reference to the patient's name) with the help of a patient identification number, transmitted to the responsible data-processing agency and evaluated.

In the event of a revocation of consent to the study by the patient, including further data collection, no further data will be collected from the time of revocation. The data collected so far will continue to be used and evaluated within the study. If a patient only discontinues the study treatment, the data required for the study can continue to be collected and used.

11. ethical concerns, legal and administrative regulations

11.1 Declaration of Helsinki and Good Clinical Practice

The study will be conducted in accordance with the ethical principles originating in the Declaration of Helsinki [*Ref.*]. The current version of the Declaration will be observed.

The recommendations of Good Clinical Practice [*Ref.*], valid since 17.1.1997, are taken into account where applicable.

11.2 Ethics Committees

The study protocol is submitted with the required further documents to the responsible lead ethics committee of the study director with a request for evaluation. The study can only begin after the Ethics Committee has given its approval.

The Ethics Committees of the participating trial centres receive a copy of the positive evaluation of the first Ethics Committee and the documents required for the "second vote". Each participating trial site will receive copies of the positive evaluation of the first ethics committee and of its responsible ethics committee for the trial site file.

11.3 Subsequent changes

The study protocol must be adhered to. Any deviation from the planned examination and treatment measures or times for which the investigator is responsible must be documented and justified (e.g. emergency measures).

Changes or additions to the study protocol can only be initiated and authorised by the study management. The lead ethics committee and the ethics committees of the participating trial centres will be informed of any changes to the study protocol. If necessary, their approval will be sought again. Changes requiring evaluation may not be implemented before the decision of the ethics committee.

Changes to the study assessed by the Ethics Committee that are appropriate,

- have an impact on the safety of the persons concerned,
- additional data collection or evaluations that require a change in patient information and/or consent,
- influence the interpretation of the scientific documents on which the study is based or the scientific validity of the study results,
- substantially change the way the study is managed or conducted,

may only be made if these changes have been approved by the Ethics Committee.

11.4 Legal regulations

11.5 **Patient insurance/proband insurance**

-not applicable

11.6 **Registration**

The study is to be registered in the following public register: *www.clinicaltrial.gov.*

11.7 Funding

The study is financed through budgetary funds.

11.8 Final report and publication

The publication of the study results will take place regardless of how the results turn out.

12. literature

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