

# Evaluating the usefulness of CT-scans in the diagnosis and management of chronic obstructive pulmonary disease (COPD) patients with respiratory symptoms.

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<b>Registration date</b> 10/12/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 19/12/2024	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Chronic obstructive pulmonary disease (COPD) is a type of obstructive lung disease characterized by long-term breathing problems and poor airflow. The main symptoms include shortness of breath and cough with sputum production. COPD is a progressive disease, meaning it typically worsens over time.

COPD is a major health problem worldwide accounting for more than 3 million deaths annually. Usually, COPD-related deaths occur during an acute exacerbation of COPD.

The primary objective of the proposed clinical trial is to evaluate the impact of a chest CT scan on the recovery of COPD patients having an exacerbation of their respiratory symptoms.

### Who can participate?

People diagnosed or suspected with COPD, aged 40 years or above, with a smoking history of over 20 pack years

### What does the study involve?

Patients will be randomized into two groups. Patients allocated in group A will have a CT scan whereas patients allocated in group B will have an x-ray. The study personnel will also perform follow-up phone calls and/or visits, as needed, to the patients to remind them to complete the EXACT. Furthermore, the patients will be monitored for adherence to treatment that have been given by the study physician after diagnosis.

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

There are no added risks to the patients as there is currently no clear guideline regarding the use or not use of CT scans during AECOPD. Emerging data suggest that there is a decrease in mortality in smokers who undergo CT scans as a control against bronchial carcinoma.

Where is the study run from?

University Hospital Basel, Clinic for Respiratory Medicine and Pulmonary Cell Research  
(Switzerland)

When is the study starting and how long is it expected to run for?

November 2019 to March 2024

Who is funding the study?

University Hospital Basel (Switzerland)

Who is the main contact?

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## Contact information

### Type(s)

Scientific

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# Additional identifiers

## Protocol serial number

Rescue\_Version 3

# Study information

## Scientific Title

Respiratory Exacerbation Symptoms in COPD Undergoing Evaluation – The RESCUE study: Evaluating the usefulness of CT-scans in the diagnosis and management of COPD patients with exacerbations of respiratory symptoms. A randomised, interventional, controlled, non-inferiority study

## Acronym

RESCUE

## Study objectives

The recovery of COPD patients, presenting at the emergency department, is similar between COPD patients who have a chest CT scan and COPD patients undergoing chest x-ray but who do not have a chest CT scan at presentation for an acute exacerbation of respiratory symptoms.

## Ethics approval required

Ethics approval required

## Ethics approval(s)

approved 12/12/2019, Ethikkommission Nordwest- und Zentralschweiz (EKNZ; Ethics Committee northwest- and central Switzerland) (Hebelstrasse 53, Basel, 4056, Switzerland; +41 (0)61 268 13 50; eknz@bs.ch), ref: 2019-01920

## Study design

Multicenter randomized interventional controlled non-inferiority study

## Primary study design

Interventional

## Study type(s)

Diagnostic

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

Diagnosis and management of COPD patients with exacerbation of respiratory symptoms

## Interventions

Patients will be randomized 1:1 and will be allocated in two groups. Patients allocated in group A will have a CT-scan whereas patients allocated in group B will have an x-ray. Patients from group B with a high probability of pulmonary embolism and D-dimers >0.5 µg/ml or CRP >25 mg/L or PCT >0.25 µg/L will also have a CT scan.

All additional management of patients in both groups, will be based on current recommended clinical practice guidelines. In case of clinical indication, attending physicians will be able to diverge from the study protocol and perform thorax-CTs irrespective of study group

randomization.

At baseline, the following data will be collected: demographic data, medical history, comorbidities, medication, clinical assessment and laboratory values (CRP, pro-calcitonin, D-dimers, pro-BNP). The CAT, MMRC, as well as the DECAF score will be fulfilled. Furthermore, we will collect nasopharyngeal swabs and spontaneous sputum for microbiological and microbiome analysis. Serum samples will also be collected and properly stored for subsequent analysis. Chest radiography will be performed using a standardized protocol. At this stage, the attending emergency physician will provide the most probable diagnosis and will decide if patients will be discharged or admitted to the appropriate hospital unit where they will be treated according to unit procedures. The physician will also outline the therapeutic plan with bronchodilators, inhaled corticosteroids, antibiotics or anticoagulants. The therapeutic plan will include initiation of treatment as well as modification or discontinuation of an existing treatment. Patients will be instructed to fill in the EXACT questionnaire at admission and then on day 7, 14, 21, and 28, each evening before bedtime.

The study personnel will also perform follow-up phone calls and/or visits (when patient is hospitalised), as needed, to the patients to remind them to complete the EXACT. Furthermore, the patients will be monitored for adherence to treatment that have been given by the study physician after diagnosis.

Furthermore, using the COPD-version of our big imaging data analysis software based on Image J algorithms embedded in an Apache-Spark environment for large scale cloud computing (<https://github.com/4Quant/COPD-staging>), developed in cooperation with 4Quant (ETH spin-off in Zürich), we will evaluate the potential of quantitative imaging biomarkers in relation to patients' management and recovery.

The projecting value of a CT-scan in the accurate diagnosis and effective management of COPD patients will be assessed by evaluating the 7 days EXACT questionnaires. Patients will be asked to return to the hospital for a follow up at Day 30. Next to the clinical and lung functional evaluation, CAT, and MMRC will be fulfilled and nasopharyngeal swabs and spontaneous sputum for microbiological and microbiome analysis will be collected. Serum samples will also be collected and properly stored for subsequent analysis.

## **Intervention Type**

Procedure/Surgery

## **Primary outcome(s)**

1. Length of hospital stay measured in days reviewing the medical records
2. Diagnosis and therapy recorded before radiographic finding, after radiographic finding and at discharge by the treating physician

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

1. Symptoms measured using the EXACT score questionnaire at baseline, 7, 14, 21 and 28 days
2. COPD assessment test (CAT score questionnaire) at baseline and 30 (+7) days
3. Modified Medical Research Council (MMRC) dyspnea scale at 28 days
4. Circulating biomarkers of COPD severity and outcome measured using blood sample at 28 days
5. Mortality up to 30 (+7) days measured using patient records
6. DECAF score for acute exacerbation measured through Dyspnoea (Questionnaire), Eosinopenia (blood), Consolidation (radiographic finding), Acidaemia (blood gas analysis) and atrial fibrillation (electrocardiogram) at baseline

## **Completion date**

01/03/2024

## Eligibility

### Key inclusion criteria

1. Diagnosed or suspected COPD
2. Able to give informed consent as documented by signature
3. Age  $\geq 40$  years
4. Smoking history  $\geq 20$  PY
5. Suspicion of exacerbation of respiratory symptoms

### Participant type(s)

Patient

### Healthy volunteers allowed

No

### Age group

Adult

### Lower age limit

40 years

### Sex

All

### Total final enrolment

28

### Key exclusion criteria

1. Pregnant or lactating women
2. Inability or contraindications to undergo a CT-scan eg. pregnancy
3. Clinically significant concomitant diseases such as organ transplantation
4. Acute coronary syndrome – emergency angiography
5. Inability to follow the procedures of the study, e.g. due to language problems, dementia, etc.

### Date of first enrolment

15/01/2020

### Date of final enrolment

01/03/2024

## Locations

### Countries of recruitment

Germany

Greece

Switzerland

**Study participating centre****University Hospital Basel**

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## Sponsor information

**Organisation**

University Hospital of Basel

**ROR**

<https://ror.org/04k51q396>

## Funder(s)

**Funder type**

Hospital/treatment centre

**Funder Name**

Universitätsspital Basel

**Alternative Name(s)**

University Hospital Basel, University Hospital of Basel, The University Hospital Basel, Hôpital Universitaire de Bâle, L'Hôpital universitaire de Bâle, Das Universitätsspital Basel, UHB

**Funding Body Type**

Government organisation

**Funding Body Subtype**

Other non-profit organizations

**Location**

Switzerland

## Results and Publications

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

**IPD sharing plan summary**

Available on request