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

Submission date
01/12/2020

Recruitment status
No longer recruiting

Registration date
10/12/2020

Overall study status
Completed

Last Edited
19/12/2024

Condition category
Respiratory

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

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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, Ethikkomission 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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)

Diagnostic

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet.

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 measure
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

Secondary outcome measures
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

Overall study start date
01/11/2019

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 ≥40 years
4. Smoking history ≥20 PY
5. Suspicion of exacerbation of respiratory symptoms

Participant type(s)
Patient

Age group
Adult

Lower age limit
40 Years

Sex
Both

Target number of participants
310

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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Study participating centre
University Hospital of Ioannina
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Sponsor type
Hospital/treatment centre

Website
https://www.unispital-basel.ch/

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

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
31/12/2026

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