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Investigating immune cells in the lungs of people with severe community-acquired pneumonia

Submission date 20/12/2019	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 06/01/2020	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 03/01/2020	**Condition category** Respiratory	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims

Community-acquired pneumonia (CAP) is an infection of the lungs where the lungs become inflamed. Severe CAP requires admission to hospital in specialised areas with increased nursing care such as intensive care (ICU) and may require the temporary support of a breathing machine (mechanical ventilation). In England pneumonia is the most common infection-related cause for ICU admission and UK data indicates that up to a third of patients admitted to an ICU with pneumonia die. Additionally, there is a large economic cost and survivors are often left with significant reductions in their quality of life.

Immune responses in the lung need to balance identification and clearance of disease-causing microbes with the collateral damage of lung inflammation and injury. Of particular interest are local immune cells that play a crucial role in protecting the lung against bacteria and viruses. These specialised immune cells remain in the lung and cannot be detected in the circulating blood of patients, so samples of lung cells must be taken.

This study will investigate local immune cells in mechanically ventilated patients with severe CAP. Studying the local immune response to severe CAP offers insights into how this disease occurs, may help decide which patients are going to need to most support and may identify new treatment targets for this important condition.

Who can participate?

People admitted to intensive care at Oxford University Hospitals Foundation NHS Trust who require mechanical ventilation

What does the study involve?

Doctors use samples taken from lung fluid to detect infection. This study will use the excess samples to measure the levels of immune cells in the lung fluid. The lung fluid is collected using a process called bronchoalveolar lavage. This involves passing a tube from the patient's mouth or nose into the lung, squirting in some saline (salt solution) and then sucking it back up the tube so that any cells or substances in the lung fluid can be examined.

What are the possible benefits and risks of participating?
There are no specific benefits to participating in this study and taking part in this study will not affect participants' care in any way. The lung fluid samples would be taken anyway as part of routine medical care.

Where is the study run from?
The Kadoorie Centre for Critical Care Research (UK)

When is the study starting and how long is it expected to run for?
February 2019 to January 2021

Who is funding the study?
Oxford University (UK)

Who is the main contact?
Christopher Andersen, christopher.andersen@ndcn.ox.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
263517

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
PID 14303, IRAS 263517

Study information

Scientific Title
ImmuneCAP: T-cell responses in severe community acquired pneumonia, a pilot observational study

Acronym
ImmuneCAP

Study objectives
Community acquired pneumonia (CAP) is a pathogen-driven inflammatory process of the lung parenchyma characterised by an exudative infiltration of alveolae causing impairment of lung function. Our understanding of the underlying processes associated with this condition is incomplete. In this study we will study the local immune responses in pneumonia through analysis of bronchioalveolar lavage fluid.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 30/10/2019, Yorkshire & The Humber – Leeds East Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ; +44 (0)207 1048 088), ref: 19/YH/0289

Study design
Cross-sectional observational study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Other

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

Health condition(s) or problem(s) studied
Community-acquired pneumonia

Interventions

This observational study will compare consented patients with severe acute pneumonia to consented patients with and without lung injury. Once enrolled in the study, the participant will have a bronchoalveolar lavage sample taken and will be followed up for 90 days or until hospital discharge.

Intervention Type
Procedure/Surgery

Primary outcome measure
Quantity and phenotype of lung-derived T-cell populations measured using flow cytometry at a single timepoint within 72 h of the establishment of mechanical ventilation

Secondary outcome measures
Severity of respiratory failure and other organ failure using the sequential organ failure assessment (SOFA) score during the 90 days following admittance or the period from hospital admittance to discharge

Overall study start date
01/02/2019

Completion date
20/01/2021

Eligibility

Key inclusion criteria
1. Admitted to a critical care setting in the Oxford University Hospital Trust
2. Mechanically ventilated for less than 72 h
3. Diagnosis of community acquired pneumonia has been made by the treating physicians based on the following criteria:
3.1. Symptoms and/or signs consistent with a lower respiratory tract infection
3.2. Radiological evidence of new onset consolidation on a chest x-ray or CT scan
4. Aged ≥16 years
5. Able to consent themselves or declaration obtained from a personal or professional consultee

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
15

Key exclusion criteria

1. Previously included in the study
2. Hospital admission in the past 30 days (prior to this current presentation)
3. Long-term resident of a nursing home or other residential care facility

Date of first enrolment
21/12/2019

Date of final enrolment
20/10/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Oxford University Hospitals Foundation NHS Trust
Kadoorie Centre, Level 3
John Radcliffe Hospital
Headington
Oxford
United Kingdom
OX3 9DU

Sponsor information

Organisation
University of Oxford

Sponsor details
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Sponsor type
University/education

Website
http://www.ox.ac.uk/

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
University/education

Funder Name
Medical Sciences Division, University of Oxford

Results and Publications

Publication and dissemination plan
The results of this study will be published in a peer-reviewed journal and presented at local, national and international meetings. Authorship will be determined in accordance with the ICMJE guidelines and other contributors will be acknowledged. The results of the study will be summarised on the Critical Care Research Group webpages: https://www.ndcn.ox.ac.uk/research/critical-care-research-group-kadooriecentre .

Intention to publish date
01/06/2021

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during this study will be included in the subsequent results publication.

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?
HRA research summary			28/06/2023	No	No