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

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	Recruitment status No longer recruiting Overall study status Completed Condition category Respiratory

- ] Prospectively registered
- Statistical analysis plan
- ] 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

**Contact name** Dr Christopher Andersen

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#### **Contact details**

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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

Clinical Trials Research Group Boundary Brook House Churchill Drive Headington Oxford England United Kingdom OX3 7GB +44 01865 616480 ctrg@admin.ox.ac.uk

#### 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