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A pan-pandemic respiratory infection surveillance study

Submission date
01/03/2021

Recruitment status
No longer recruiting

Registration date
03/03/2021

Overall study status
Completed

Last Edited
18/09/2025

Condition category
Respiratory

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

Plain English summary of protocol

Background and study aims
Acute lower respiratory tract disease affects large numbers of people worldwide. Older people are more likely to have disease, suffering both reduced quality of life and increased mortality (death) from respiratory infection. Previous studies have tried to define the burden of respiratory infection in adults, but these studies have been limited as they required patients to have either an identified cause of disease (microbiological diagnosis) or change on a chest X-ray (radiological diagnosis). This has led to an underestimate in disease in adults, because other cases have not been counted.
In 2019, a new virus called SARS-CoV-2 (also referred to as coronavirus) that causes an illness known as COVID-19 emerged and is causing a worldwide pandemic. As the virus is new to humans, people do not have any immunity to it and large numbers of patients are expected to become infected. Researchers do not understand fully how this virus causes disease, nor the risk factors for a poor outcome (including death). They also do not understand how this virus interacts with other bacteria and viruses that cause disease in humans. This is important because if they can determine how these infections interact with each other and the consequences for the patients affected, they may be able to offer better vaccination strategies to prevent disease and treatments to help patients affected. Other diseases important in adult respiratory infection are pneumococcus and RSV (a cold virus). There are potential new vaccines available for use in adults, but as the true amount of disease caused by these infections is not known, researchers cannot determine if using these vaccines in adults would be worthwhile.
The Avon CAP study aims to record all patients admitted with respiratory illness at two hospitals in the Bristol area. The researchers will gather data that has already been recorded by the clinical teams treating these patients, including demographics, comorbidities (other illnesses), outcomes and the results of the investigations undertaken by the medical team. Persons with acute respiratory illness will also be offered participation in the consented portion of this study involving additional testing for pneumococcal and RSV infection, which will identify more cases of such infections than routine testing. The researchers will then use these data to accurately define the true amount of disease caused by respiratory illness and be able to determine the subgroups of disease (for example by patient comorbidity, microbiological and radiological diagnosis) and determine the impact of COVID-19 on respiratory disease.

Who can participate?
Any adult aged 18 and over who is admitted to hospital at one of the participating hospitals in the Bristol area, UK.

What does the study involve?
The study will collect data already used and gathered in the clinical care of patients. This will include demographic data (e.g. age, gender, smoking status); participant's comorbidities (e.g. asthma, heart disease, diabetes); vaccination status (e.g. COVID-19 vaccine); clinical presentation (signs/symptoms on admission to hospital, clinical observations such as heart rate); the results of investigations undertaken by the clinical care team (e.g. chest X-ray, blood tests, microbiological tests including COVID-19 results); clinical outcomes (e.g. length of hospital stay, mortality at 30 days, need for organ support or intensive care). The researchers will ask participants to allow them to take either primary research samples (blood, urine and respiratory) or use leftover samples taken from routine clinical care to try to identify respiratory infections.

What are the possible benefits and risks of participating?
There are no direct benefits to taking part in this study, however, participants may feel that they are contributing to the scientific knowledge about COVID-19 and vaccine-preventable infections during the pandemic which may help diagnostics, vaccine development, and future patient care. The collection of nasal/throat swabs, saliva, blood and urine samples are not thought to pose a significant risk to study participants.
As with all research data of this kind, there are risks to study participants concerning the collection and use of data (e.g. potential identification of study participants, inappropriate access to data). In order to ensure that data protection requirements concerning identifiable data collected through this study, and the right to privacy and confidentiality are maintained, the study will have approval under Section 251 of the NHS Act, undertaken appropriate Data Security Toolkit Assessments, and ensured that all protocols and organisations adhere to GDPR compliance.

Where is the study run from?
The study is a University of Bristol study that is operating at North Bristol and University Hospital Weston NHS Trusts (UK)

When is the study starting and how long is it expected to run for?
August 2019 to July 2025

Who is funding the study?
The study is an investigator-led project funded under a collaborative agreement with Pfizer (USA)

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
283899

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 283899

Study information

Scientific Title
Avon Community-Acquired Pneumonia (AvonCAP) study: a pan-pandemic acute lower respiratory tract disease surveillance study

Acronym
AvonCAP

Study objectives
Accurate incidence rates of acute lower respiratory tract disease (LRTD) and its disease subsets, such as pneumonia and LRTI, remain elusive and the impact of COVID-19 on respiratory disease burden is unclear. Accurate incidence rates of vaccine-preventable infection are required to assess the potential population-level impact of vaccination recommendations. As discussed,

current evidence suggests that the burden of pneumococcal and RSV lower respiratory infections is underestimated. Further, the current COVID-19 pandemic due to SARS-CoV-2 has dramatically increased the burden of LRTI worldwide. On this basis, the researchers seek to conduct a study to measure the true burden of acute respiratory disease due to these pathogens during and after the COVID-19 pandemic within the limitations of currently available diagnostic testing.

This population-based multi-hospital, active prospective surveillance is designed to determine population-based incidence rates of hospitalized adults ≥18 years of age with community-acquired LRTI (including CAP) in Bristol, England. The involved Bristol hospitals' nearly completely capture hospital admissions among residents of a well-delineated geographic region allowing for the calculation of population-based incidence rates of LRTI. Study data derived from surveillance activities will fully enumerate the number of acute LRTD cases in this region.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 05/06/2020, East of England - Essex Research Ethics Committee (Health Research Authority, Skipton House, 80 London Road, London, SE1 6LH, UK; +44 (0)20 7972 2545; hra.approval@nhs.net), REC ref: 20/EE/0157

Study design
Observational epidemiological study

Primary study design
Observational

Study type(s)
Screening

Health condition(s) or problem(s) studied
Acute lower respiratory tract disease (LRTD) - which encompasses pneumonia, lower respiratory tract infection (LRTI), acute bronchitis, exacerbation of underlying respiratory disease including asthma and chronic obstructive pulmonary disease (COPD), as well as COVID-19 (SARS-CoV-2 infection)

Interventions
Adults with LRTD will be screened using population-level surveillance at study hospitals, and the collection of standard-of-care data will be performed on all LRTD events. Patients presenting during the recruitment period of the study, with documented or suspected COVID-19 will fulfil study eligibility criteria, and therefore all references to LRTD also encompass documented or suspected COVID-19 cases who may not otherwise qualify as LRTD. LRTD patients will be offered participation in the enhanced diagnostic testing portion of this study with informed consent, which will involve the collection of urine, respiratory, and in some cases blood samples, for additional testing, if necessary, for COVID-19, pneumococcus, and RSV as well as administration of a short patient questionnaire on COVID-related risk behaviours. The pneumococcal testing will include serotype to allow estimation of the proportion of the burden that is potentially vaccine-preventable – either by the currently available PCV13 or the anticipated PCV20, which is currently in the final phases of clinical development. Information about the additional pneumococcal, SARS-CoV-2 and RSV infection testing will be integrated

with the population-level surveillance data to allow for more accurate population-based estimates of vaccine-preventable pneumococcal and COVID-19 and RSV-related LRTD incidence. The epidemiologic data generated from the study may serve as the baseline for future vaccine effectiveness studies

Intervention Type
Other

Primary outcome(s)
The population-based incidence of community-acquired LRTI hospitalizations during and following the COVID-19 pandemic, overall and for community-acquired pneumonia, obtained from the medical admission records within participating hospitals and analysed yearly for 3 years, with interim analyses carried out as required

Key secondary outcome(s))
Obtained from the medical admission records within participating hospitals and analysed yearly for 3 years, with interim analyses carried out as required:

COVID-19/SARS-CoV-2 infection:
1. The population-based incidence rates of COVID-19-related hospitalizations
2. The proportion of LRTI hospitalizations (overall, standard-of-care pneumonia diagnosis, radiologically confirmed CAP only) attributable to COVID-19, both overall and by age/risk stratification
3. Demographics, clinical and epidemiological characteristics and outcomes within COVID-19 LRTI and the different subcategories, both overall and stratified by age/risk
4. Mortality rate at 30 days after admission to hospital for COVID-19 LRTI and its subcategories, overall and by age group and risk group status
5. The association between COVID-19 and other respiratory pathogens, including but not limited to S. pneumoniae, influenza and RSV, both with co- and super-imposed infection and secondary respiratory infection
6. The length of hospital stay for COVID-19 LRTI hospitalizations and the proportion of COVID-19 admissions involving an ICU stay, determined by review of clinical records and medical notes on day 30 following admission
7. The association of S. pneumoniae LRTI with more severe COVID-19 clinical outcomes (such as requiring invasive mechanical ventilation) among persons hospitalised with COVID-19 infection

Streptococcus pneumoniae:
1. The population-based incidence rates of hospitalizations for the following 12 specified LRTI subcategories:
1.1. All LRTI (overall, pneumococcal only, PCV13-type, and PCV20-type);
1.2. Any standard-of-care pneumonia diagnosis (overall, pneumococcal only, PCV13-type, and PCV20-type);
1.3. Any radiologically confirmed CAP (overall, pneumococcal only, PCV13-type, and PCV20-type).
2. The proportion of LRTI hospitalizations (overall, standard-of-care pneumonia diagnosis, radiologically confirmed CAP only) associated with any S. pneumoniae, PCV13, PCV20 serotypes and by individual serotypes, both overall and stratified by age/risk condition
3. Demographics, clinical and epidemiological characteristics and outcomes within LRTI and its 12 subcategories, both overall and stratified by age/risk condition
4. Mortality rate for LRTI (and its 12 subcategories), overall and by age group and risk group status, determined by review of clinical records and medical notes on day 30 following admission
5. The serotype and frequency and type of antibiotic resistance among S. pneumoniae isolates

6. The length of hospital stay for LRTI hospitalizations and the proportion of LRTI admissions involving an ICU stay, overall and by 12 subcategories

RSV Infection:
1. The population-based incidence of RSV LRTI hospitalizations both overall and stratified by presence of underlying risk conditions
2. The clinical and epidemiological characteristics and clinical outcomes of RSV-related LRTI hospitalizations both overall and stratified by presence of underlying risk conditions
3. The proportion of LRTI caused by RSV in hospitalized patients both overall and stratified by presence of underlying risk conditions
4. The difference between the population-based incidence of hospitalization, epidemiology, clinical presentation, and outcomes observed in RSV-positive adults versus those with other common respiratory viruses (eg, SARS-CoV-2 and influenza)
5. The pathogen distribution rates of RSV, SARS-CoV-2, and other viral pathogens among adults admitted with congestive heart failure or chronic obstructive pulmonary disease exacerbations

COVID-19 vaccine effectiveness:
These measures may each be assessed per vaccine brand or manufacturer in the real-world setting. Vaccine effectiveness will be defined as 1-Odds Ratio of being vaccinated.
Primary:
The effectiveness of two doses of COVID-19 vaccine (i.e. fully vaccinated) against hospitalization for acute respiratory infection due to SARS-CoV-2 infection by vaccine brand or manufacturer
Secondary:
1. The effectiveness of only 1 dose of COVID-19 vaccine (i.e., partially vaccinated) against hospitalization due to SARS-CoV-2 infection by vaccine brand/manufacturer
2. The effectiveness of ≥1 dose of COVID-19 vaccine (i.e., ever vaccinated) against hospitalization for ARI due to SARS-CoV-2 infection by vaccine brand/manufacturer
3. The effectiveness of current and future COVID-19 vaccinations by COVID-19 variant in real-world settings

Completion date
31/07/2025

Eligibility

Key inclusion criteria
1. Aged ≥18 years of age
2. Patients with illness with the following two characteristics:
2.1. Acute illness (i.e., present for 28 days or less) AND
2.2. Evidence of acute LRTD:
2.2.1. Patients with current or suspected COVID-19 or previous proven COVID-19 within last 28 days OR
2.2.2. Clinical or radiologic diagnosis of pneumonia or an acute LRTI OR
2.2.3. New onset or worsening of ≥2 of the following eight LRTD symptoms or clinical findings:
2.2.3.1. Fever (>38.0°C) or hypothermia (<35.5°C) before or within 24 hours of enrolment
2.2.3.2. Pleuritic chest pain
2.2.3.3. Cough (including nocturnal only)
2.2.3.4. Sputum production or purulence
2.2.3.5. Dyspnea (shortness of breath) including orthopnea or on exertion only
2.2.3.6. Tachypnea (respiratory rate ≥20/min) documented by healthcare professional
2.2.3.7. Abnormal auscultatory findings suggestive of LRTD (e.g., crepitations/rales or evidence

of pulmonary consolidation including dullness on percussion, bronchial breath sounds, wheezing, or egophony)
2.2.3.8. Radiologic finding that is consistent with LRTD, including pneumonia, and/or acute congestive heart failure (e.g., pleural effusion, increased pulmonary density due to infection, the presence of alveolar infiltrates [multilobar, lobar or segmental] containing air bronchograms, or interstitial oedema)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
46722

Key exclusion criteria
Patients meeting any of the following criteria will not be included in the study:
1. Any patient who develops signs and symptoms of LRTD after being hospitalized for ≥48 hours (either at current hospital, another transferring hospital, or a combination of these), unless admitted with current, previous proven, or suspected COVID-19 infection.
2. Previously enrolled participants readmitted ≤7 days after discharge for their study qualifying admission, unless admitted with current, previous proven, or suspected COVID-19 infection
3. At the time of enrolment, an LRTD-related diagnosis has been excluded or another diagnosis confirmed (for example, patient was found to have fever and tachypnoea due to an intraabdominal process such as cholecystitis)

Date of first enrolment
01/08/2020

Date of final enrolment
30/07/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Southmead Hospital
North Bristol NHS Trust
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Study participating centre
Bristol Royal Infirmary
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Sponsor information

Organisation
University of Bristol

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Industry

Funder Name
Pfizer

Alternative Name(s)
Pfizer Inc., Pfizer Consumer Healthcare, Davis, Charles Pfizer & Company, Warner-Lambert, King Pharmaceuticals, Wyeth Pharmaceuticals, Seagen, Pfizer Inc

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan

Participant level information cannot be made available publicly as it is sensitive and would breach patient confidentiality. Data may be available in a truly anonymised fashion through request. Data will be held in a database within each participating NHS Trust and a unifying database within the University of Bristol, in compliance with GDPR and approval from the Confidentiality Advisory Group.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Improving the accuracy of Respiratory Syncytial Virus (RSV) incidence estimates among hospitalised adults in Bristol, UK	21/08/2025	22/08/2025	Yes	No
HRA research summary			28/06/2023	No	No
Interim results article	non-peer-reviewed interim results on effectiveness of first dose of COVID-19 vaccines in preprint	03/03/2021	19/03/2021	Yes	No
Interim results article	Effectiveness of BNT162b2 and ChAdOx1 nCoV-19 COVID-19 vaccination at preventing hospitalisations in people aged at least 80 years	01/11/2021	07/12/2021	Yes	No
Interim results article	Incidence of community acquired lower respiratory tract disease in Bristol, UK during the COVID-19 pandemic	08/08/2022	17/10/2022	Yes	No
Interim results article	Effectiveness of BNT162b2 COVID-19 vaccination in prevention of hospitalisations and severe disease in adults with SARS-CoV-2 Delta (B. 1.617.2) and Omicron (B.1.1.529) variant between June 2021 and July 2022	07/12/2022	13/12/2022	Yes	No
Interim results article	Severity of Omicron (B.1.1.529) and Delta (B.1.617.2) SARS-CoV-2 infection among hospitalised adults	11/12/2022	13/12/2022	Yes	No
Interim results article	Effectiveness of BNT162b2 COVID-19 vaccination in prevention of hospitalisations and severe disease in adults with SARS-CoV-2 Delta (B. 1.617.2) and Omicron (B.1.1.529) variant between June 2021 and July 2022: a prospective test negative case–control study	07/12/2022	18/09/2025	Yes	No
Interim results article	Effectiveness of BNT162b2 and ChAdOx1 nCoV-19 COVID-19 vaccination at preventing hospitalisations in people aged at least 80 years: a test-negative, case-control study	23/06/2021	18/09/2025	Yes	No
Interim results article	Incidence of community acquired lower respiratory tract disease in Bristol, UK during the COVID-19 pandemic: A prospective cohort study	08/08/2022	18/09/2025	Yes	No

Interim results article	Severity of Omicron (B.1.1.529) and Delta (B.1.617.2) SARS-CoV-2 infection among hospitalised adults: a prospective cohort study in Bristol, United Kingdom	11/12/2022	18/09/2025	Yes	No
Participant information sheet	version 1.2		01/04/2021	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 3.0	25/02/2022	13/06/2022	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes