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Understanding viral infection and respiratory symptoms following admission to hospital

Submission date
01/06/2022

Recruitment status
No longer recruiting

Registration date
09/08/2022

Overall study status
Ongoing

Last Edited
04/02/2026

Condition category
Infections and Infestations

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
The majority of winter pressures facing NHS hospital trusts are as a result of acute respiratory viral infections. Whilst many patients recover without the need for hospitalisation, a small number go on to develop severe disease. This study aims to better understand the different responses between individuals to respiratory viral infections, and why some patients become more unwell than others. The researchers hope to identify new ways to spot respiratory diseases. The aim is to understand the time to full recovery and identify factors that favour a more rapid recovery or predispose to a slower recovery.

Who can participate?
Patients aged 18 years and over who present in a hospital setting with a suspected respiratory viral infection

What does the study involve?
A nose and throat swab will be collected, and a point of care to test to determine if the participant has a respiratory viral infection will be carried out. Only those who test positive for a respiratory viral infection will go on to stage 2 of the study, although all participants who consent will have baseline data recorded. In stage 2, further nose and throat swabs and blood samples will be collected on days 1, 3 and 7 of enrolment. As well as completing questionnaires about how they are feeling while in hospital, participants will complete questionnaires following discharge from hospital at pre-specified time points up to 26 weeks later.

What are the possible benefits and risks of participating?
This study is an observational study, so participants will receive no treatment different from standard of care, but the study will help researchers to better understand the course of respiratory viral infections. This may help aid the treatment of patients in the future as well as the development of new treatments. The risks of this study are no greater than that of standard care. Nose/throat swabs might cause some mild discomfort, and the taking of blood may cause bruising around the area, light pain or dizziness. All procedures as part of the study are carried out by trained healthcare professionals.

When is the study starting and how long is it expected to run for?
November 2021 to June 2026

Where is the study run from?
Southampton General Hospital (UK)

Who is funding the study?
1. Janssen Pharmaceuticals (USA)
2. AstraZeneca (UK)

Who is the main contact?
UNIVERSAL Study Team
UNIVERSAL@soton.ac.uk

Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
309464

Central Portfolio Management System (CPMS)
53752

Study information

Scientific Title
Understanding Infection, Viral Exacerbation and Respiratory Symptoms at Admission - Longitudinal (UNIVERSAL) study

Acronym
UNIVERSAL

Study objectives
The recent COVID-19 pandemic highlighted the need to link clinical care with research for a more rapid translation of new treatment discoveries. The majority of winter pressures facing NHS acute trusts are as a result of acute respiratory viral infection. Whilst many patients recover without the need for hospitalisation, a small proportion goes on to develop severe disease. A better understanding of the natural history of acute respiratory viral infection and recovery will facilitate improved clinical management with the potential to identify options for intervention in those at risk of more severe disease.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/07/2022, West Midlands – Coventry and Warwickshire Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)207 104 8009; coventryandwarwick.rec@hra.nhs.uk), ref: 22/WM/0119

Study design
Prospective longitudinal observational database

Primary study design
Observational

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Respiratory viral infections

Interventions
This is an observational cohort study to develop a prospective longitudinal clinical database. All adults admitted with respiratory syndromes to participating hospital sites will be asked to participate in the study. Those who test positive for respiratory viral infection will be enrolled into the study and provide samples. Those who consent and test negative will have baseline data collection only.

Those who test positive will give blood samples and nose and throat samples on days 1, 3 and 7 following consent. They will also complete a number of different patient-reported outcome questionnaires (EQ-5D-5L, RiiQ, FluPRO PLUS) at a number of timepoints until 26 weeks post-enrolment. They will also complete a post-viral infection questionnaire at 6, 12 and 26 weeks comprised of three validated questionnaires.

Intervention Type
Other

Primary outcome(s)
1. The incidence rate of different respiratory viruses in admitted, samples patient population measured using descriptive statistics during the winter season (a 1-year period) across UK sites

2. Clinical and biological predictors of progression of disease, recovery and length of stay in admitted, samples patient population measured using multiple logistic regression analysis with backward selection during the winter season (a 1-year period) across UK sites

Key secondary outcome(s))
1. Time to recovery for different viruses and patient factors measured using univariate analyses at baseline/recovery
2. Cost estimate per patient based on Healthcare Resource Group (HRG) coding at baseline /discharge

Completion date
30/06/2026

Eligibility

Key inclusion criteria
Current inclusion criteria as of 09/09/2022:
Stage 1
1. Aged ≥18 years
2. Has symptoms of an acute respiratory illness (ARI)
3. Is a respiratory inpatient

Plus, for Stage 2
3. Has positive test result for respiratory viral infection

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Previous inclusion criteria:
Stage 1
1. Aged ≥18 years old
2. Has symptoms of an acute respiratory illness (ARI)*

Plus, for Stage 2
3. Has positive test result for respiratory viral infection

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex

All

Total final enrolment
1011

Key exclusion criteria
1. Combined nasal and throat swabbing cannot be performed (patient decision or contraindication to procedure)
2. Consent declined or consultee consent declined
3. Previously recruited into this study

Date of first enrolment
17/06/2022

Date of final enrolment
31/12/2025

Locations

Countries of recruitment
United Kingdom

England

Scotland

Study participating centre
Southampton General Hospital
Tremona Road
Southampton
England
SO16 6YD

Study participating centre
Ninewells Hospital
Ninewells Avenue
Dundee
Scotland
DD1 9SY

Sponsor information

Organisation

University Hospital Southampton NHS Foundation Trust

ROR
https://ror.org/0485axj58

Funder(s)

Funder type
Industry

Funder Name
Janssen Pharmaceuticals

Alternative Name(s)
Janssen Pharmaceutica NV, JANSSEN-CILAG NV, Janssen Belgium, Janssen, Janssen Pharmaceuticals

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Belgium

Funder Name
AstraZeneca

Alternative Name(s)
AstraZeneca PLC, Pearl Therapeutics, AZ

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request. As a minimum, anonymous data will be available for request from 3 months after the publication of an article, to researchers who provide a completed Data Sharing request form that describes a methodologically sound proposal, for the purpose of the approved proposal and if appropriate a signed Data Sharing Agreement. Data will be shared once all parties have signed relevant data sharing documentation.

Researchers interested in our data are asked to complete the Request for Data Sharing form (CTU/FORM/5219) [template located on the SCTU website, https://www.southampton.ac.uk/ctu] to provide a brief research proposal on how they wish to use the data. It will include; the objectives, what data are requested, timelines for use, intellectual property and publication rights, data release definition in the contract and participant informed consent etc. If considered necessary, a Data Sharing Agreement from Sponsor may be required.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		09/04/2025	23/04/2025	Yes	No
HRA research summary			28/06/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes