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Performance of 3 host response tests in acute respiratory infection

Submission date 07/02/2025	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 16/05/2025	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 23/06/2025	**Condition category** Respiratory	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
Many patients come to hospital with infection of their respiratory tract. Although most are caused by viruses, patients are often given antibiotics, which do not work against viruses. This is because doctors cannot tell if the illness is caused by viruses or bacteria just from their symptoms, or by using current tests, and so they usually give antibiotics ‘just in case’ it might be bacterial.

Unfortunately, this overuse of antibiotics can be harmful to patients and also leads to antimicrobial resistance, where antibiotics stop being effective.

There are some new tests that look at a patient's immune response and can tell the difference between bacterial and viral infection. Some of these are very quick and are referred to as ‘point-of-care tests’. These could be used in hospital emergency departments to reduce overuse of antibiotics. However, there is not enough data at the moment to be sure they are accurate or that they can actually stop doctors giving antibiotics when a viral infection is present, and a bacterial infection is absent. There are currently 2 new tests that have been approved for use in the UK and one that will be approved shortly.

The aim of this study is to assess the accuracy of three different point-of-care tests in distinguishing bacterial vs viral infection in respiratory tract infection

Who can participate?
Adult patients that present to the Emergency Department (ED) or the Acute Medical Unit (AMU) at University Hospital Southampton with symptoms of acute respiratory illness within the 24 hours of arrival in ED or AMU.

What does the study involve?
Potential participants will be approached and consented by the research team for the taking of additional blood samples alongside those taken for routine clinical care and two nasal pharyngeal swabs. Also a finger-prick blood sample for will be taken at the bedside.

Patient care will not be altered from routine clinical care as clinical staff and participants will not be informed of the results of the Febri-Dx test or retrospective MeMed-BV or Inflammatix TriVerity test results.

What are the possible benefits and risks of participating?
There is no individual benefits for participating patients as the results of the Febri-DX or MeMed-BV or Inflammatix TriVerity results will not be relayed to the patient or clinical team, as the main purpose of the study is to investigate diagnostic accuracy of these tests, which are not currently used as routine part of clinical care. However, all participants may feel that they are helping to improve the NHS care for unwell patients in the future by being part of this research. No greater risk to patients enrolled in this study is anticipated than those present during routine clinical care. The harms associated with finger-prick blood tests and respiratory swabbing is minimal and typically mild and short-lived discomfort at the time these tests are preformed.

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

When is the study starting and how long is it expected to run for?
January 2025 to January 2028

Who is funding the study?
NIHR CRN Fund (UK)
Biomedical Research Council (UK)
Investigator initiated and funded

Who is the main contact?
1. Professor Tristan Clark (Chief Investigator), t.w.clark@soton.ac.uk
2. Dr Rebecca Wong (Co-investigator), rebecca.wong@uhs.nhs.uk
3. Dr Alex Tanner (Co-investigator), alex.tanner@uhs.nhs.uk

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
324613

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
RHM MED2094, SRB0044

Study information

Scientific Title
Comparison of the performance of 3 Host Immune ResPonse tests for distinguishing bacterial and viral acute respiratory infection

Acronym
CHIRP

Study objectives
This study aims to evaluate the diagnostic accuracy of three different host response tests in patients presenting to the Emergency Department or Acute Medical Unit with acute respiratory infection (ARI).

ARI will remain a burden on healthcare services and the diagnostic uncertainty of the underlying infective aetiology and antimicrobial prescribing will continue for years to come. Recently new host response tests have been developed as 'point-of-care' tests which could preform better than the current biomarkers (CRP, WBC, PCT). This could offer scope to improve antimicrobial prescribing habits.

Should these new host response tests demonstrate better accuracy than the existing biomarkers it could offer the scope for further studies assessing the impact into their role on antibiotic prescribing in ARI.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 10/01/2025, North West - Greater Manchester Central Research Ethics Committee (3rd Floor Barlow House, Minshull Street, Manchester, M1 3DZ, United Kingdom; +44 2071048057; gmcentral.rec@hra.nhs.uk), ref: 23/NW/0060

Study design
Single-centre observational retrospective diagnostic accuracy study

Primary study design
Observational

Secondary study design
Diagnostic accuracy study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Comparing diagnostic accuracy of 3 different host response tests in acute respiratory illness in adults

Interventions
This study will consist of a diagnostic accuracy study comparing 3 different host response tests (Febri-Dx, MeMed BV, Inflammatix TriVerity) in response to acute respiratory infection, in the form of a prospectively recruited study. Adult patients presenting to ED or Acute Medical Unit with symptoms susceptive of acute respiratory infection will be recruited and samples will be collected. Recruits will have a point-of-care Febri-Dx taken at enrolment and further blood samples will be stored for retrospective Inflammatix TriVerity and MeMed BV testing. Two nasopharyngeal swabs will be collected - one to test for viral respiratory infections needed to help guide clinical adjudication and the other frozen if further diagnostic work is needed. Additionally, serum, EDTA and Paxgene samples will be stored if further diagnostic work is needed.

The results of the FebriDx/MeMed BV/TriVerity test will not be made available to the patient or treating clinical staff in the emergency department or acute medical unit. The routine nasopharyngeal swab for viral pathogen result will be available as part of routine clinical care.

Acute patient participation in the study will end after sample collection. Due to the low risk and brief nature of the patient involvement in the study, and that no routine deviation from routine clinical care is planned, no active observation and follow-up of patients post participation is needed. Routine outcome date will be collected.

Blinded clinical adjudication of infectious status (non, viral, bacterial, co-infection) will be the reference standard which diagnostic accuracy is calculated. Positive Percentage Agreement (PPA), Negative Percentage Agreement (NPA), Positive Predictive Value (PPV), Negative Predictive Value (NPV), Overall accuracy, AUROC, all with 95% confidence intervals.

A secondary exploratory objective includes evaluating the equivalence of EDTA blood and Paxgene RNA blood on gene expression values for other novel host response tests in development. This will be assessed through correlation, Spearman's Coefficient and Kappa statistics.

Intervention Type

Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
MeMed BV, Inflammatix TriVerity, Febri-Dx

Primary outcome measure
Baseline characteristics and observations, routine biomakers (CRP, WBC, PCT) and respiratory viral PCR swab results. These results will be collected from the patient record from admission to ED/AMU. These results will be used for blinded clinical adjudication as the bases for diagnostic accuracy of the Febri-Dx, MeMed BV, Inflammatix TriVerity test.

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
10/01/2025

Completion date
10/01/2028

Eligibility

Key inclusion criteria
1. Is a patient in the ED or AMU, Southampton General Hospital, UHS
2. Aged ≥18 years old
3. Able to be recruited and sampled within 24 hours of arrival in the ED or AMU
4. Has the capacity to consent to the study
5. Has at least one of the following acute respiratory symptoms:
5.1. Cough
5.2. Shortness of breath
5.3. Coryza
5.4. Sore Throat
5.5. Wheeze
5.6. Fever (where not definitively explained by another cause)
5.7. Reported exacerbation of a chronic respiratory condition (e.g., asthma, COPD)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
200

Key exclusion criteria
1. Not fulfilling all inclusion criteria
2. Declines nasal/pharyngeal swabbing, finger prick testing or venesection
3. Underlying severe bronchiectasis, cystic fibrosis, severe immune suppression

Date of first enrolment
10/02/2025

Date of final enrolment
31/07/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University Hospital Southampton
Tremona Road
Southampton
United Kingdom
SO16 6YD

Sponsor information

Organisation
University Hospital Southampton NHS Foundation Trust

Sponsor details
Southampton General Hospital, Tremona Road
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Sponsor type
Hospital/treatment centre

Website
http://www.uhs.nhs.uk/home.aspx

ROR
https://ror.org/0485axj58

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Biomedical Research Centre

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
1. Planned publication in high-impacted peer reviewed journals
2. Dissemination via medical conferences as posters and presentations

Intention to publish date
28/02/2026

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Professor Tristan Clark (CI) from 10/02/2025
t.w.clark@soton.ac.uk

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 2.1	26/04/2023	10/02/2025	No	Yes
Protocol file	version 1.0	10/01/2025	10/02/2025	No	No
Protocol file	version 1.1	16/05/2025	27/05/2025	No	No