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Ultra-rapid point-of-care testing for viruses and host response

Submission date 20/10/2023	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 20/10/2023	**Overall study status** Ongoing	
Last Edited 21/01/2025	**Condition category** Infections and Infestations	

Plain English summary of protocol

Background and study aims
Infection by respiratory viruses, including influenza ('flu') and SARS-CoV-2 (which causes COVID-19), can lead to serious illnesses. Antibiotics do not work against viral illnesses unless there is also a bacterial infection present at the same time. Unfortunately, people with respiratory virus infections are often given antibiotics when they might not need them. This unnecessary use of antibiotics can harm patients and promote antibiotic resistance. The aim of this study is to find out if combining three ultra-rapid tests looking for markers of respiratory virus infections and bacterial infections makes a difference or not to patients in terms of receiving antibiotics and other treatments.

Who can participate?
Patients aged 18 years and over with respiratory illness in the Emergency Department

What does the study involve?
The researchers will ask the participants a few brief questions about their symptoms and their health. A computer program will then assign participants randomly to receive either point-of-care testing or standard (i.e., usual) clinical care. All participants are asked to have a nasopharyngeal swab. A nasopharyngeal swab is a thin swab that is put into the nose and goes behind the nose into the nasal passages. It can feel odd and uncomfortable but only takes a few seconds. Participants in the point-of-care testing group are asked for a finger prick blood test too.

What are the possible benefits and risks of participating?
The researchers cannot guarantee any benefits. Participants might be contributing to improved patient care in the future. Having a nasopharyngeal swab and a finger prick can be uncomfortable but these procedures are completed very quickly. The researchers also carefully monitor the treatment outcomes of patients for safety.

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

When is the study starting and how long is it expected to run for?
October 2023 to June 2026

Who is funding the study?
The study is funded by a grant to the hospital and University of Southampton researchers from bioMérieux, the company that manufactures the rapid respiratory virus swab test. The company has no influence over the design or management of the trial and has no access to the participants' information or any samples that they provide. Personal identifiable information does not leave the hospital.

Who is the main contact?
Dr Nathan Brendish, n.brendish@soton.ac.uk and nathan.brendish@uhs.nhs.uk

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
330292

Protocol serial number
CPMS 58031, IRAS 330292

Study information

Scientific Title

The clinical impact of ultra-rapid syndromic molecular point-of-care testing for respiratory viruses combined with finger-prick host response testing in adults presenting to the emergency department with acute respiratory illness: a pilot randomised controlled trial (UltraPOC)

Acronym
UltraPOC

Study objectives
It is hypothesised that point-of-care testing for respiratory viruses combined with host response testing, done as early as possible in the patient journey in the Emergency Department in patients with acute respiratory illness, will reduce antibiotic use.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/10/2023, South Central – Hampshire B (Meets via Zoom therefore no set venue; +44 (0)207 104 8088, +44 (0)207 104 8289, +44 (0)207 104 8189; hampshireb.rec@hra.nhs.uk), ref: 23/SC/0294

Study design
Randomized; Interventional; Design type: Diagnosis, Other

Primary study design
Interventional

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Respiratory viruses

Interventions
This is a pilot randomized controlled trial. As a pilot study, there is no formal sample size calculation. It is based in the Emergency Department at Southampton General Hospital.

Adult patients with acute respiratory illness in Southampton General Hospital's Emergency Department will be identified and assessed for eligibility for the trial. Potential participants would have been seen and assessed by the triage nurse or other triaging clinician but may not have been fully treated by their clinician. The triage nurse or other triage clinician may highlight potential participants to the study team. Potential participants will receive a participant information sheet, and be invited to ask questions, as part of the informed written consent process.

Once consent has been obtained, participants will be enrolled once they have been randomized using the electronic randomisation service. Participants will be randomized (1 to 1) to be in either the point-of-care testing group (intervention) or the standard clinical care group (control group).

Participants in the point-of-care testing group will receive an ultra-rapid syndromic respiratory virus PCR test by nasopharyngeal swab, a finger-prick anti-viral host response protein MxA test, and a finger-prick CRP test. The results of all three tests will be entered into the patient's notes alongside an algorithm recommending or not recommending antibiotic use.

Participants in the control group will be asked for a nasopharyngeal swab that will be frozen and tested at least 30 days after enrolment.

All necessary patient participation is completed in a single encounter; however, selected participants in the point-of-care testing group may be asked to complete an optional survey and /or asked to provide an optional small blood sample, within 24 hours of randomisation if they are still in hospital. The patient survey will form part of public-patient involvement in future trial design.

Lastly, the researchers will survey the point-of-care test operators with a system usability scale and also survey the attitudes of staff in the ED, to inform the design of a future full trial.

Intervention Type
Other

Primary outcome(s)
The proportion of participants who received antibiotics in the Emergency Department (ED), including patients discharged from the ED with a prescription for antibiotics. Measured from electronic patient medical records up until 30 days.

Key secondary outcome(s))
Unless otherwise specified, all outcome measures are measured from electronic patient medical records up until 30 days:

Clinical:
Antibiotic-related:
1. The proportion of participants who received antibiotics in the ED
2. The proportion of patients who were discharged from the ED with an antibiotic prescription
3. The median duration of antibiotics, in days
4. The median duration of oral antibiotics, in days
5. The median duration of intravenous antibiotics, in days
6. The proportion of patients who received only a single ("stat") dose of antibiotics
7. The proportion of patients who received antibiotics for less than 48 hours duration

Other treatment-related:
1. The proportion of patients with influenza who received an influenza antiviral medication
2. The proportion of patients who did not have influenza who received antiviral medication
3. The median duration of time from arrival in ED to the first dose of influenza antiviral medication in patients, in patients with influenza and treated with an influenza antiviral medication
4. The proportion of patients with COVID-19 treated who met guidelines for treatment with dexamethasone who received dexamethasone
5. The proportion of patients with COVID-19 treated who met guidelines for treatment with a COVID-19 antiviral medication who received a COVID-19 antiviral medication

Other:
1. The median time from arrival in ED to respiratory virus PCR results, in minutes
2. The proportion of patients tested by PCR for respiratory viruses
3. The proportion of patients tested by PCR by a panel of more than four respiratory viruses
4. The median duration of time to C-reactive protein results, minutes
5. The median duration of time in the ED, in minutes
6. The proportion of patients admitted to hospital from the ED
7. The proportion of patients where the treating clinician has been adherent to the treatment algorithm as guided by point-of-care testing results in the ED, within the intervention group
8. The median time from arrival in ED to all three point-of-care test results being available, in the intervention group

Safety:
1. The median duration of hospital admission, in days
2. The proportion of patients representing to ED within 14 days but not admitted
3. The proportion of patients admitted to hospital within 14 days, who had not initially been admitted
4. The proportion of patients readmitted to hospital within 14 days
5. The proportion of patients who died within 14 days of enrolment
6. The proportion of patients who died within 30 days of enrolment
7. The proportion of patients who received care in an intensive care unit during admission within 14 days of enrolment
8. The proportion of patients not initially receiving antibiotics, who subsequently received antibiotics for the same condition within 7 days
9. The proportion of patients who saw a General Practitioner within 14 days of enrolment
10. The proportion of respiratory virus infections not detected (i.e., “missed”) by routine clinical care but subsequently detected by stored frozen sample testing by PCR, in the control group

Pilot-related:
These outcomes will not be evaluated between groups unless indicated
1. The proportion of test failures for each of the point-of-care test devices within the intervention group
2. The diagnostic accuracy measures (sensitivity, specificity, positive predictive value, negative predictive value) for the SPOTFIRE point-of-care PCR for common respiratory viruses (influenza, SARS-CoV-2, RSV) compared to the hospital’s contemporaneous PCR testing pathway
3. The proportion of participants approached to enter the trial but not enrolled (“screen failures”)
4. The proportion of patients who were withdrawn from the study, overall and both groups
5. The proportion of patients with complete data for clinical secondary outcome measures, overall and both groups
6. The median time to randomisation from arrival in the ED
7. The median time between randomisation and point-of-care PCR result, in the intervention group
8. The number of failed randomisations, in total and both groups

Completion date
30/06/2026

Eligibility

Key inclusion criteria

1. Is a patient in the ED Southampton General Hospital, UHS
2. Aged >=18 years old
3. Able to be randomised within four hours of arrival in the ED
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) (acute or worsening symptoms must be of 7 days or less duration)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Not fulfilling all inclusion criteria
2. Declines nasal/pharyngeal swabbing or finger prick testing
3. Underlying severe bronchiectasis, cystic fibrosis, severe immune suppression, or another condition where antibiotic use is mandated according to local guidelines
4. A palliative management approach has been decided by the clinical team or appears likely to the investigator
5. Investigator discretion

Date of first enrolment
01/09/2025

Date of final enrolment
01/05/2026

Locations

Countries of recruitment
United Kingdom

England

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

Sponsor information

Organisation
University Hospital Southampton NHS Foundation Trust

ROR
https://ror.org/0485axj58

Funder(s)

Funder type
Industry

Funder Name
bioMérieux; Grant Codes: BFD-RST-23-001

Alternative Name(s)
bioMérieux SA, bioMérieux, Inc.

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
France

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from the Chief Investigator, Dr Nathan Brendish, n.brendish@soton.ac.uk and nathan.brendish@uhs.nhs.uk

IPD sharing plan summary

Available on request