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Randomised controlled trial comparing point-of-care testing for respiratory viruses with standard clinical care in adults hospitalised with acute respiratory illness

Submission date
24/12/2014

Recruitment status
No longer recruiting

Registration date
14/01/2015

Overall study status
Completed

Last Edited
21/06/2019

Condition category
Respiratory

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

Plain English summary of protocol

Background and study aims
Respiratory viruses, including the influenza virus, cause large numbers of people to become unwell and be admitted to hospital every winter. The current diagnostic tests for respiratory viruses are done in laboratories away from patients and are time consuming, taking more than 24 hours to generate a result for doctors. New rapid tests for respiratory viruses have been developed that can be done in admission units and give results within 1 hour. These tests have equivalent accuracy to the standard laboratory tests and are licensed for clinical use in Europe and the USA. Introducing these new tests to admission units might improve the identification and management of patients infected with respiratory viruses and could also improve infection control practices to stop the spread of viruses within hospitals. Identifying viruses at an early stage of a patient's care might also lead to a reduction in antibiotic use, which is important in reducing the spread of antibiotic resistance in hospitals. These changes might lead to an overall reduction in the costs for the National Health Service and its institutions. The aim of this study is to assess whether a test can improve people's health, help them take fewer antibiotics and help them be less likely to end up in hospitals.

Who can participate?
Patients with a respiratory infection caused by viruses

What does the study involve?
Patients presenting to a hospital with respiratory illness are randomly allocated to have a rapid test for respiratory viruses in addition to standard care or to standard care alone.

What are the possible benefits and risks of participating?
Improvement in clinical care, reduction in antibiotic use and reduction in the cost of hospital admissions

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

When is the study starting and how long is it expected to run for?
January 2015 to December 2016

Who is funding the study?
University of Southampton, Faculty of Medicine (UK)

Who is the main contact?
Dr Tristan Clark

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
RHM MED 1217

Study information

Scientific Title
Comparison of point-of-care testing for respiratory viruses with standard clinical care in adults presenting to secondary care with acute respiratory illness (ResPOC): a randomised controlled study

Acronym
ResPOC

Study objectives
Point-of-care testing for respiratory viruses in adults hospitalised with acute respiratory illness might reduce antibiotic use, improve use of influenza treatments, improve use of isolation facilities and might reduce overall costs of hospitalisation compared with standard clinical care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Research Ethics Service Committee North West - Preston (UK), 05/12/2014, ref: 14/NW /1467
Substantial amendments approved 09/07/2015 and 02/02/2016

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Acute respiratory illness

Interventions
Participants are enrolled and assigned a study number consequently. Patients are randomised 1: 1 to the intervention or control groups using an online randomisation service (sealed envelope. com). Blinding is not attempted.

Intervention group: A nose and throat swab will be taken by a member of research staff (doctor or nurse) according to standard protocols. Swabs are placed directly into viral transport medium. The sample is analysed on the FilmArray Respiratory Panel as per training delivered by the apparatus manufacturer. Test results are normally available within 1 hour using the FilmArray Respiratory Panel. In the event of a run failure, the analysis run will be repeated using the same sample.
The results of the test will be documented in the patient's case notes and in the event of a pathogen being detected, a doctor from the clinical team responsible for the patient will be directly informed. The participant will also be informed of the result on the same day.

Control:
These patients will be managed using standard clinical care. Respiratory virus testing using lab RT-PCT will be at the discretion of the responsible clinical team.

There is no follow up for study participants. Outcomes are collected retrospectively from case notes for the entire duration of hospitalisation or at 30 days, whichever is shortest.

Intervention Type
Device

Primary outcome(s)
Proportion of patients treated with antibiotics: measured retrospectively from case notes for the entire duration of hospitalisation or at 30 days, whichever is shortest

Key secondary outcome(s)

Secondary outcome measures as of 27/09/2016:
The outcomes will be measured retrospectively from case notes for the entire duration of hospitalisation or at 30 days, whichever is shortest.
1. Duration of antibiotic use
2. Proportion of patients receiving only a stat dose of antibiotics
3. Proportion of patients receiving <48 hours antibiotics
4. Proportion of patients treated with antiviral drugs
5. Time to antiviral drug use
6. Duration of antiviral drugs
7. Duration of hospital stay
8. Proportion of patients nursed in a side room
9. Duration of side room use
10.Time to allocation of a side room
11. Health care utilisation

Original secondary outcome measures:
The outcomes will be measured retrospectively from case notes for the entire duration of hospitalisation or at 30 days, whichever is shortest.
1. Duration of antibiotic use
2. Proportion of patients treated with antiviral drugs
3. Time to antiviral drug use
4. Duration of antiviral drugs
5. Duration of hospital stay
6. Proportion of patients seen by a nurse in a side room
7. Time to allocation to a side room
8. Number of investigations done

Completion date
30/04/2016

Eligibility

Key inclusion criteria
1. Aged 18 years old or over
2. Capacity to provide written informed consent and is able and willing to adhere to the study procedures
3. Is a patient at Southampton General Hospital Acute Medical Unit (AMU) or Emergency Department (ED)
4. Can be recruited to the study within 24 hours of first triage by ED staff or within 24 hours of arrival on AMU (if admitted directly to AMU)
5. Has an acute respiratory illness and/or fever >37.5°C
6. Duration of illness less than or equal to 7 days

An episode of acute respiratory illness is defined as an acute pulmonary illness (including pneumonia, bronchitis and influenza-like illness) or an acute exacerbation of a chronic respiratory illness (including exacerbation of chronic obstructive pulmonary disease, asthma or bronchiectasis).

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. A palliative approach is being taken by the treating clinicians
2. Previously included in this study (first season only)
3. Declines nasal or pharyngeal swabbing

Date of first enrolment
15/01/2015

Date of final enrolment
31/12/2016

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University Hospitals Southampton Foundation NHS Trust
University Hospitals Southampton, Tremona Road, Southampton
Southampton
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Sponsor information

Organisation
University Hospital Southampton Foundation NHS Trust

ROR
https://ror.org/0485axj58

Funder(s)

Funder type
University/education

Funder Name
University of Southampton

Alternative Name(s)
University of Southampton UK

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2017		Yes	No
Protocol article	protocol	06/02/2017		Yes	No
HRA research summary			28/06/2023	No	No
Other publications	post-hoc analysis	09/08/2018		Yes	No