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A controlled clinical trial investigating the impact of point of care testing for ‘atypical’ pneumonia, bordetella pertussis and viral pathogens on patient pathways, antimicrobial consumption and cost-efficiency.

Submission date
30/06/2015

Recruitment status
No longer recruiting

Registration date
06/11/2015

Overall study status
Completed

Last Edited
19/10/2017

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims

Viral respiratory tract infections (i.e. viral infections of the sinuses, throat, airways or lungs) are a significant burden on the NHS particularly during the annual winter influenza epidemic. Most cases are managed either by the patient's GP's or in the Emergency Department (ED). GP’s surgeries and EDs, where patients are seen for a short time only, don't have timely access to diagnostic tests for respiratory viruses. The diagnosis is therefore a clinical one and where there is doubt, a number of these infections will be managed with unnecessary antibiotics in order to treat potential, undiagnosed bacterial infection. A proportion of all cases will also require hospital admission, wirh the patient having to be placed in isolation in a neutral or negative pressure side room. In one study, respiratory viruses were found to be responsible for 12.8% of patients with community acquired pneumonia (CAP) admitted to hospital in the UK. If undiagnosed and unisolated in the hospital, there is the potential for affected patients to pass the infection to others in the hospital (cross-transmission) which can lead to outbreaks of infection in a ward or even the hospital as a whole. As respiratory virus infections can affect staff as well as patients, the extreme consequences of unisolated cases are ward closures, and an increase in the number of people becoming ill or even dying. Mycoplasma pneumoniae and Chlamydophila pneumoniae (atypical pathogens) and Bordetella pertussis ('pertussis' or 'whooping cough') respiratory tract infections are often diagnosed clinically while waiting for laboratory results to come back, which take days. Laboratory tests don’t always perform well. Again, patients may be unnecessarily prescribed antibiotics and/or admitted to hospital. Increase illness and death rates may result from missed diagnoses. Providing a result for the detection of respiratory viruses, Mycoplasma, Chlamydophila & Pertussis in the Medical Admission when the patient is first seen, using point of care testing may avoid the issues highlighted, provide better quality of care, allow for better use of resources and reduce inappropriate antibiotic use and the development of antibiotic resistance. The aim of this study is to find out whether rapidly diagnosing whether an infection is caused by the any of the respiratory viruses, Mycoplasma

pneumoniae, Chlamydophila pneumoniae and Bordetella pertussis at point of care in the Medical Admissions Units reduces unnecessary antibiotic use and length of hospital stay when compared to standard routine laboratory based tests.

Who can participate?
Patients aged at least 16 with a acute upper respiratory tract infection.

What does the study involve?
Participants are randomly allocated into one of two groups. Combined nose and throat swabs for standard respiratory virus testing are taken for patients in group 1 (control group). Combined nose and throat swabs for respiratory virus testing with the point of care PCR test are taken for patients in group 2. The two types of tests are then assessed by looking at, among other things, antibiotic use and length of hospital stay for all patients taking part in the study.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
King's College Hospital NHS Foundation Trust (UK)

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

Who is funding the study?
Biomerieux (UK)

Who is the main contact?
Dakshika Jeyaratnam

Contact information

Type(s)
Scientific

Contact name
Dr Dakshika Jeyaratnam

Contact details
King's College Hospital London
Denmark Hill
London
United Kingdom
SE5 9RS

Additional identifiers

Study information

Scientific Title
Point of care testing for respiratory pathogens

Acronym
RESP MAU POCT

Study objectives
To determine whether or not a rapid result for respiratory viruses, Mycoplasma pneumoniae, Chlamydophila pneumoniae and Bordetella pertussis at point of care in the Medical Admissions Units reduces unnecessary antibiotic use and length of hospital stay when compared to standard routine laboratory based tests.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee London - Westminster, 17/11/2014, ref: 14/LO/1703

Primary study design
Interventional

Study design
Interventional single-centre study

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Rapid PCR-based diagnostic test when placed at the point of care

Interventions
1. Control: combined nose and throat swabs for respiratory virus testing with the laboratory - based PCR testing +/- atypical investigations e.g. serology
2. Intervention: combined nose and throat swabs for respiratory virus testing with the point of care PCR test

Intervention Type
Device

Primary outcome(s)
Antibiotic use and length of hospital stay

Key secondary outcome(s)
1. Turnaround time of tests
2. Readmission rate
3. Mortality
4. Ease of use of Point of Care Test
5. Cost benefit

Completion date
01/07/2015

Eligibility

Key inclusion criteria
1. ≥ 16 years of age
2. Have mental capacity to give written informed consent to participate in the study
3. Have acute upper respiratory tract infection or influenza-like illness +/- lower respiratory tract infection. Symptoms include fever or feeling feverish (chills), cough, sore throat, runny or stuffy nose, muscle-aches or body-aches, headaches, fatigue (tiredness), some people may have vomiting or diarrhoea (though this is more common in children than adults). Please note that not all patients with influenza have fever.

Please note that patients with a clinical or radiological diagnosis of community-acquired lower respiratory tract infection, evidence/suspicion of bacterial infection with common, 'typical' respiratory tract pathogens, patients with known or suspected immune suppression, and those with sepsis or severe sepsis are also eligible for inclusion.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Those who do NOT meet the inclusion criteria
2. Evidence/suspicion of bacterial infection affecting sites other than the respiratory tract

Date of first enrolment
05/01/2015

Date of final enrolment
01/07/2015

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
King's College Hospital NHS Foundation Trust
Cheyne Wing
Bessemer Road
Denmark Hill

London
United Kingdom
SE5 9RS

Sponsor information

Organisation
King's College Hospital

ROR
https://ror.org/01qz4yx77

Funder(s)

Funder type
Industry

Funder Name
Biomerieux (UK)

Funder Name
CLAHRC South London (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	10/10/2017		Yes	No
HRA research summary			28/06/2023	No	No