

Randomised controlled trial to evaluate impact of diagnostic testing for influenza, respiratory syncytial virus, Streptococcus pneumoniae infection on the management of acute admissions in the elderly and high-risk 18-64 year old

Submission date 24/03/2005	Recruitment status No longer recruiting	☒ Prospectively registered
Registration date 30/03/2005	Overall study status Completed	☐ Protocol
Last Edited 02/06/2014	Condition category Infections and Infestations	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Karl Nicholson

Contact details
Infectious Diseases Unit
Level 6 Windsor Building
Leicester Royal Infirmary
Leicester
United Kingdom
LE1 5WW
+44 (0)116 2586952
karlgnicholson@doctors.org.uk

Additional identifiers

Protocol serial number

Study information

Scientific Title

Study objectives

This is a prospective, randomised controlled trial that evaluates the impact of rapid diagnostic testing for influenza, respiratory syncytial virus and streptococcus pneumoniae, on the management and outcome of acute cardio-pulmonary admissions in the elderly (age >65 years), and 'high risk' individuals with underlying chronic heart or lung disease, including asthma, who are >18 years of age. The cost effectiveness of near patient and rapid molecular tests will also be assessed.

Please note that, as of 11/05/2009, the anticipated end date has been updated from 31/10/2008 to 30/04/2009.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied

Influenza, respiratory syncytial virus (RSV) and Streptococcus pneumoniae

Interventions

Patients in each centre will be randomly allocated to one of three diagnostic groups:

Group 1: Near patient tests (Quidel-influenza; Binax NOW-pneumococcus)

Group 2: Rapid molecular tests (influenza and RSV) plus laboratory testing of concentrated urine in the Binax NOW assay

Group 3: Traditional laboratory culture

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Our remit from the NHS HTA is to determine the diagnostic accuracy and clinical and cost effectiveness of rapid molecular and near patient test for influenza, RSV, and S pneumoniae, in comparison to traditional laboratory culture. There are a number of outcome measures: The impact of test results on prescribing, clinical outcomes (length of stay, ITU admissions, ventilatory support, deaths), quality of life and use of isolation facilities.

Key secondary outcome(s)

Financial outcome measures: Total costs of diagnostic tests, total care costs, cost savings and effectiveness (cost per case detected and cost per QALY). Laboratory outcome measures: Diagnostic accuracy (sensitivity, specificity, positive and negative predictive values, ease of tests and speed of tests. Observational outcomes: Estimated admission rates for influenza, RSV and S pneumoniae.

Completion date

30/04/2009

Eligibility

Key inclusion criteria

1. Age >65 years or age >18 years with underlying chronic heart or lung disease including asthma
2. Have an acute exacerbation of chronic cardio-pulmonary illness of <120 hours (5 days) duration or an acute cardio-pulmonary illness or influenza-like illness of <5 days duration, including: pneumonia, influenza/influenza-like illness, exacerbations of chronic obstructive pulmonary disease (COPD), bronchitis, asthma, congestive heart failure, cardiac arrhythmia

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Senior

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Inclusion criteria not met
2. Angina
3. Suspected myocardial infarction
4. Dementia
5. Psychotic disorder
6. Cardio-pulmonary illness that is so severe that the patient can not provide written informed consent

Date of first enrolment

01/11/2005

Date of final enrolment

30/04/2009

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Infectious Diseases Unit

Leicester

United Kingdom

LE1 5WW

Sponsor information

Organisation

University Hospitals of Leicester NHS Trust (UK)

ROR

<https://ror.org/02fha3693>

Funder(s)

Funder type

Government

Funder Name

NIHR Health Technology Assessment Programme - HTA (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	01/05/2014		Yes	No