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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

Registration date
30/03/2005

Overall study status
Completed

Last Edited
02/06/2014

Condition category
Infections and Infestations

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 03/39/18

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

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Diagnostic

Participant information sheet

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 measure
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.

Secondary outcome measures
Financial outcome measures: Total costs of diagnostic tests, total care costs, cost savings and effectiveness (cost per case detected and cost per QUALY). 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.

Overall study start date
01/11/2005

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

Age group
Senior

Lower age limit
18 Years

Sex
Both

Target number of participants
2750

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
England

United Kingdom

Study participating centre
Infectious Diseases Unit
Leicester
United Kingdom
LE1 5WW

Sponsor information

Organisation
University Hospitals of Leicester NHS Trust (UK)

Sponsor details
Glenfield Hospital
Groby Road
Leicester

England
United Kingdom
LE3 9QP

Sponsor type
University/education

Website
http://www.uhl-tr.nhs.uk/

ROR
https://ror.org/02fha3693

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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