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Surveillance of healthcare associated pathogens in hospital/community settings

Submission date
30/07/2013

Recruitment status
No longer recruiting

Registration date
10/09/2013

Overall study status
Completed

Last Edited
06/02/2017

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
Healthcare-associated infections are an important problem in hospitals and much research has been carried out on the bacteria that cause healthcare-associated infections (e.g. methicillin-resistant Staphylococcus aureus (MRSA) and Clostridium difficile) and the measures to control them. More recently, organisms that are resistant to many antibiotics, such as multi-drug resistant Gram-negative bacilli (MDR GNB) and vancomcyin-resistant enterococci (VRE), have become a problem in hospitals and are now a focus of research. In contrast, there has been little or no research done about healthcare-associated infections in community settings such as nursing homes. However, many people living in nursing homes are at risk of infection with these bacteria because of their underlying medical condition, antibiotic treatment, and contact with hospital either as an outpatient or an inpatient. The aim of this study is to look at the frequency of these organisms at Addenbrookes hospital and in the nursing home. This involves collection of samples for laboratory testing in order to identify the organisms that cause healthcare-associated infections (e.g. MRSA, C. difficile, MDR GNB and VRE). Genetic fingerprinting (whole genome sequencing) of the bacteria is also performed in order to understand the movement of organisms between patients and between the hospital and community setting.

Who can participate?
All patients admitted to Addenbrookes hospital and residents in a nursing home in Cambridge during the study period.

What does the study involve?
In the hospital, samples for testing are collected when indicated as part of routine clinical care. In the nursing home, samples are taken up to once a week for the duration of the study. The samples include swabs from the patient's nose, throat, groin, and any open wounds or ulcers. Samples of urine are also collected (if there is a urinary catheter) and stool (faeces). If a stool sample is not available then a rectal (bottom) swab is collected. Some clinical information is also collected from medical records. There are no study-specific interventions and all patients receive routine clinical care.

What are the possible benefits and risks of participating?
There are no direct benefits to the participant for taking part in the study. However, the

information obtained from the study may help future patients and reduce the risk of healthcare-associated infections. There are no risks to the participant from taking part in the study. Having the samples taken may be mildly uncomfortable but does not hurt.

Where is the study run from?
The study is being run by the Cambridge University Hospitals NHS Foundation Trust and the University of Cambridge (UK).

When is the study starting and how long is it expected to run for?
October 2013 to October 2014

Who is funding the study?
The Wellcome Trust and the Department of Health (UK)

Who is the main contact?
Professor Sharon Peacock
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

NH001

Study information

Scientific Title
A prospective surveillance study to define rates of carriage, transmission and infection by healthcare-associated pathogens in adjacent hospital and community settings

Study objectives
To determine the rates of carriage, transmission, and infection by specified healthcare-associated pathogens (MRSA, C. difficile, MDR GNB and VRE) in hospital and nursing home settings, using a combination of epidemiological investigation and bacterial whole genome sequencing.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES committee: London Queen Square, 03/02/2014, ref: 13/LO/1278

Study design
Prospective observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Healthcare associated pathogens e.g. Methicillin resistant Staphylococcus aureus (MRSA), Clostridium difficile, multidrug resistant Gram negative bacteria (MDR GNB), vancomycin resistant enterococci (VRE)

Interventions
A study of patients admitted to Addenbrooke's hospital and a nursing home during the one year study period.

The frequency of carriage and infection with healthcare-associated bacteria will be determined by microbiological testing. Transmission of healthcare-associated bacteria will be determined using bacterial whole-genome sequencing.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Rate of carriage of MRSA, C. difficile, MDR GNB and VRE over time in hospital and nursing home populations
2. Rate of transmission of MRSA, C. difficile, MDR GNB and VRE over time within and between hospital and nursing home populations
3. Incidence of healthcare-associated infections by MRSA, C. difficile, MDR GNB and VRE over time in hospital and nursing home populations

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/10/2013

Completion date
01/10/2014

Eligibility

Key inclusion criteria
1. Inpatient at Addenbrookes hospital OR nursing home resident
2. Age 1 day to no upper age limit
3. Male or female
4. Microbiological testing for MRSA, C. difficile, MDR GNB, or VRE carriage or infection

Participant type(s)
Patient

Age group
All

Sex
Both

Target number of participants
65,250

Key exclusion criteria
The participant may not enter the study if they do not fulfil the inclusion criteria

Date of first enrolment
07/03/2014

Date of final enrolment
19/09/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Cambridge
Cambridge
United Kingdom
CB2 0QQ

Sponsor information

Organisation
Cambridge University Hospitals NHS Foundation Trust (UK)

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04v54gj93

Funder(s)

Funder type
Charity

Funder Name
The study is joint funded by the Wellcome Trust (reference: WT098600) and the Department of Health (reference: HICF-T5-342) through a Health Innovation Challenge Fund Grant

Results and Publications

Publication and dissemination plan
One further paper is currently under review.

Intention to publish date
06/08/2017

Individual participant data (IPD) sharing plan
The genome sequence data for the bacterial isolates publicly available after submitted to European Nucleotide Archive. Details provided in publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	12/01/2016		Yes	No
Results article	results	01/03/2016		Yes	No
Results article	results	01/08/2016		Yes	No
Results article	results	03/10/2016		Yes	No
HRA research summary			28/06/2023	No	No