

Surveillance of healthcare associated pathogens in hospital/community settings

Submission date 30/07/2013	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 10/09/2013	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 06/02/2017	Condition category Infections and Infestations	☐ 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 vancomycin-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

Contact name

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Additional identifiers

Protocol serial number

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

Primary study design

Observational

Study design

Prospective observational cohort study

Study type(s)

Screening

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(s)

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

Key secondary outcome(s)

No secondary outcome measures

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

Healthy volunteers allowed

No

Age group

All

Sex

All

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

United Kingdom

England

Study participating centre

University of Cambridge

Cambridge

United Kingdom

CB2 0QQ

Sponsor information

Organisation

Cambridge University Hospitals NHS Foundation Trust (UK)

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

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