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Study of MRSA (Methicillin-resistant Staphylococcus aureus) carriage and infection in the United Kingdom

Submission date 29/10/2011	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 21/12/2011	**Overall study status** Completed	☐ Statistical analysis plan ☒ Results
Last Edited 09/05/2018	**Condition category** Infections and Infestations	☐ Individual participant data

Plain English summary of protocol

Background and study aims

Staphylococcus aureus is a germ (bacterium) that lives on the skin and in the nose of approximately 30 in 100 people. Methicillin-resistant Staphylococcus aureus (MRSA) is a type of S.aureus that has become resistant to penicillin and similar antibiotics. Over the past few decades the incidence of MRSA infections has increased and certain strains of MRSA have become dominant in hospitals. The UK Department of Health has instituted mandatory surveillance of MRSA blood stream infections (bacteraemias) and this has resulted in a reduction in MRSA bacteraemia. However, MRSA continues to cause a considerable burden of illness and death. One of the problems in controlling MRSA infection is that we do not understand why certain MRSA strains are more successful than others or exactly how they are transmitted between patients and between hospitals. Understanding these factors will help us to identify potential control points for intervention.

Who can participate?

All individuals with MRSA carriage or infection admitted to the study hospitals may participate in the study. Participants may be any age and male or female.

What does the study involve?

We are conducting a study to look at genetic diversity and geographical distribution of MRSA in the UK. This will be achieved by collecting clinical and laboratory information and bacterial isolates from 3,300 patients with MRSA carriage and infection. We are collecting bacterial samples from these patients and performing genetic tests (whole genome sequencing) to determine the genetic differences between strains. We are examining patient movements within a hospital and between hospitals in the UK. By combining this information we hope to learn more about genetic differences in MRSA and transmission pathways. All clinical data and bacterial samples are being collected as part of routine clinical care. There are no study-specific interventions although all patients will receive treatment for MRSA colonisation or infection as part of routine clinical care.

What are the possible benefits and risks of participating?
There are no benefits to the individual patient in taking part. However, information that is obtained from the study may help to inform local infection control practices and public health policy. The risks of participation are negligible as no additional samples will be taken and no additional procedures will be performed.

Where is the study run from?
The study is being conducted by the University of Cambridge. The lead site will be the Cambridge University Hospitals NHS Foundation Trust and additional sites have been identified in England. Bacterial isolates are being sequenced at the Wellcome Trust Sanger Institute.

When is the study starting and how long is it expected to run for?
The study started in April 2012 and is expected to run for 2 years.

Who is funding the study?
The study is being funded by UK Clinical Research Collaboration (UKCRC) Translational Infection Research Initiative, the Health Protection Agency and the NIHR Cambridge Biomedical Research Centre (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
MRSA 001

Study information

Scientific Title
Study of MRSA carriage and infection in the United Kingdom: an observational cohort study

Study objectives
1. Can we use bacterial whole genome sequencing to determine MRSA phylogeography and transmission pathways in the United Kingdom?
2. Can we use phenotypic drug susceptibility (antibiograms) to track MRSA transmission within hospitals?
3. What are the relationships between clinical features, bacterial phenotype, and bacterial genotype in patients with MRSA carriage and infection in the UK?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Cambridge South Research Ethics Comittee, 24/11/2011

Study design
Observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Prevention

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
Methicillin-resistant Staphylococcus aureus (MRSA)

Interventions
Observational cohort study of patients with MRSA infection or colonisation hospitals in the United Kingdom.

There are no study-specific interventions although all patients will receive treatment for MRSA colonisation or infection as required

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Baseline clinical and demographic information
2. Outcome at hospital discharge
3. Antibiotic resistance profiles
4. Bacterial sequence data

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/01/2012

Completion date
01/01/2013

Eligibility

Key inclusion criteria
1. Patients with MRSA colonisation or infection
2. Male or female participents
3. Aged 1 day or above (no upper age limit)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
3,300

Key exclusion criteria
1. No evidence of MRSA colonisation or infection
2. No bacterial isolate available for sequencing

Date of first enrolment
01/01/2012

Date of final enrolment
01/01/2013

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)

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.cuh.org.uk/

ROR
https://ror.org/04v54gj93

Funder(s)

Funder type

Government

Funder Name
UK Clinical Research Collaboration (UKCRC) Translational Infection Research Initiative (TIRI)

Funder Name
Medical Research Council (MRC) ref: G1000803

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Health Protection Agency (HPA) (UK)

Alternative Name(s)
HPA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
NIHR Cambridge Biomedical Research Centre (UK)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Participant level data are not available. The whole genome sequences from this study have been deposited in the European Nucleotide Archive (https://www.ebi.ac.uk/ena) under study accession number PRJEB3174.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	25/10/2017		Yes	No