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MRSA POC trial

Submission date	Recruitment status	[_] Prospectively registered
20/06/2014	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
31/07/2014	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
12/04/2017	Infections and Infestations	

Plain English summary of protocol

Background and study aims
MRSA is a type of bacterial infection that is resistant to a number of widely used antibiotics. This means that it tends to be more difficult to treat than other bacterial infections. All patients admitted to a NHS hospital are tested for MRSA. Those patients found to be carriers are placed on the MRSA care pathway, which typically involves being placed in an isolation room in order to try and prevent the bacteria spreading to other patients and then treated by antibiotics to try and stop them developing an active infection. MRSA infection can be detected using a conventional culture method or via a polymerase chain reaction (PCR) based method. The PCR method gives faster results than the culture method, so, as the infected patient is placed on the MRSA pathway more quickly, one might expect the number of other patients that are then infected would be fewer compared to using the culture method. However, research into this has had mixed results with some showing no significant reduction at all. This may be due to the time needed to take the specimen to the laboratory in order to do the PCR. Point of care (POC) tests are performed in the wards by ward staff, such as nurses. This means that there is no time wasted by having to take the specimen to the laboratory. Here, we investigate whether using a POC PCR-based test will lead to a reduction of the spread of MRSA and infection rates when compared to a conventional culture based method.

Who can participate?
All adults patients admitted to one of the wards taking part in the study can participate.

What does the study involve?
Participants are randomly allocated into one of two groups. Those in the control group are swabbed for MRSA at admission and these swabs are taken to the laboratory for MRSA testing using conventional culture methods. Those in the treatment group have one set of swabs taken for conventional culture MRSA testing and one taken for POC PCR-based MRSA testing in the ward. All participants in both groups are swabbed again for MRSA infection as they are discharged. Any patient found to carriers or are infected are placed on the MRSA care pathway.

What are the possible benefits and risks of participating?
By identifying MRSA carriers rapidly, those with MRSA can be more quickly placed on the MRSA care pathway. This means that the study may reduce the chance of the infection spreading or the carrier developing an infection. The risks are minimal as MRSA swabbing is carried out already without adverse effect.

Where is the study run from?
Kings College Hospital, London (UK)

When is the study starting and how long is it expected to run for?
May 2011 to July 2012.

Who is funding the study?
Department of Health, England (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title
A trial of a rapid point of care (POC) method of MRSA detection

Study objectives
Point of care (POC) tests eliminate the need for transportation of specimens to a laboratory and they can be performed by ward staff (for example, nursing staff) at any time of day or night and do not have to be batched. Thus POC PCR-based tests should have a turn around time of as little as 70 minutes between sampling and result and should deliver the theoretical advantages of truly rapid screening. If these tests are performed on patients on admission to wards, the patients MRSA status will be known and they will be placed on the MRSA care pathway.

Ethics approval required
Old ethics approval format

Ethics approval(s)

National Research Ethics Service, 13/10/2009, ref. 09/H0709/68

Study design
It is a cluster-randomised, controlled crossover (two phases) trial design. After the first phase, the wards swap between the control arm and intervention arm for the second phase.

Primary study design
Interventional

Study type(s)
Screening

Health condition(s) or problem(s) studied
MRSA infection

Interventions
Control group: When each patient is admitted to and discharged from the ward, nursing staff will take a set of MRSA screening swabs. MRSA screening on admission is already in practice at King's College Hospital NHS foundation Trust (KCH). Nursing staff take swabs from nose, throat, perineum, skin breaks and other clinically indicated sites as per the current procedure, and send the swabs to the laboratory for MRSA detection by conventional culture methods.
Treatment group: Nursing staff will take a set of MRSA screening swabs and using a double headed swab for nose. Nursing staff will use one of doubled swab heads for POCT using the Cepheid Xpert MRSA system on the ward, and send the other swabs to the laboratory for MRSA detection using conventional culture methods.

Nursing staff will swab patients on discharge from the ward at both control arm and treatment arm. During the study, the patient will be managed as per the Trust MRSA Care Pathway. Nursing staff will manage the patient identified as MRSA positive by either POCT or culture method as per the Trust MRSA Care Pathway.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
MRSA transmission rates = the ratio of patients who are positive for MRSA by conventional microbiological method at the time of admission to the number of patients who are negative for MRSA on admission screens by conventional microbiological method and subsequently become positive by discharge on any specimen taken >48 hours after admission.

The primary outcome will be analysed using generalised estimating equations with Poisson family, log link and robust standard errors will be used to fully account for correlations of observations made within wards, periods and ward periods.

Key secondary outcome(s))
1. Appropriate and inappropriate isolation days
2. MRSA carriage rate and acquisition rate

Secondary outcomes will be measured after one month.

Completion date
31/07/2012

Eligibility

Key inclusion criteria
All adult admissions to study wards who are screened within 48 hours of admission to and discharge from the study wards are eligible for inclusion.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Patients who are:
1. MRSA positive on any specimens taken up to 5 days before the current admission
2. MRSA culture positive on study ward MRSA admission screen
3. Are not swabbed for MRSA on admission
4. Have MRSA admission screening swabs taken >48 hours after study ward admission
5. MRSA discharge screens which do not contain nose, throat and groin or perineum swabs
6. Are not swabbed for MRSA on discharge

Date of first enrolment
03/05/2011

Date of final enrolment
31/07/2012

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Department of Medical Microbiology
London

United Kingdom
SE5 9RS

Sponsor information

Organisation
Guy's & St Thomas' NHS Foundation Trust (UK)

ROR
https://ror.org/00j161312

Funder(s)

Funder type
Government

Funder Name
Department of Health, England (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	01/03/2017		Yes	No