The evaluation of rapid methicillin-resistant Staphylococcus aureus (MRSA) screening

Submission date Recruitment status [] Prospectively registered 24/04/2008 No longer recruiting [X] Protocol [] Statistical analysis plan Registration date Overall study status 30/07/2008 Completed [X] Results [] Individual participant data **Last Edited** Condition category 22/03/2010 Infections and Infestations

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number M0005186425

Study information

Scientific Title

A study of the efficacy and cost-effectiveness of methicillin-resistant Staphylococcus aureus (MRSA) screening and monitoring on surgical wards using a new, rapid molecular test

Acronym

Study objectives

Early identification of patients colonised with methicillin-resistant Staphylococcus aureus (MRSA) using rapid methods alone reduces transmission.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the East Birmingham Ethics Committee on the 17th August 2005 (ref: 05/Q2703/62).

Study design

A prospective, cluster, two period cross-over design

Primary study design

Interventional

Study type(s)

Screening

Health condition(s) or problem(s) studied

Methicillin-resistant Staphylococcus aureus (MRSA) colonisation and infection

Interventions

This is a prospective, cluster two-period cross-over design, with the only difference between the two periods being the method of MRSA detection. The study compares the use of rapid MRSA testing with the BD GeneOhm™ molecular test (BD Diagnostics - GeneOhm, CA, USA) with a standard direct inoculation culture method using chromogenic media (Biomerieux, Marcy, l Etoile, France). Wards were assigned to one of two groups, with similar wards being placed in opposite groups. The study consists of two eight-month cross-over periods, with one month follow up of study patients at the end of the final period. For the first eight month period four wards use rapid testing and standard culture methods and three wards use only standard culture methods, this is then reversed for the second eight month period. All patients are screened on admission to the ward and then every four days using a nasal swab. There was no patient follow up on discharge from the study wards.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

- 1. MRSA transmission rates
- 2. MRSA infection rates
- 3. Antibiotic prescribing levels
- 4. MRSA related morbidity
- 5. Test replicability, reliability, sensitivity/specificity, predictive positive value (PPV), negative predictive value (NPV), laboratory turn-around time

Key secondary outcome(s))

- 1. Cost of hospital episode for all patients
- 2. Post-discharge primary/community care costs and any subsequent admissions for MRSA positives
- 3. Length of stay/intensive care unit (ITU) episodes for all patients
- 4. Recovery/rehabilitation period for MRSA positives

Completion date

01/07/2007

Eligibility

Key inclusion criteria

- 1. Patients greater than 18 years of age, either sex
- 2. Admitted to seven surgical wards at Heart of England NHS Foundation Trust

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

Patients less than 18 years of age

Date of first enrolment

01/10/2005

Date of final enrolment

01/07/2007

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
West Midlands Public Health Laboratory
Birmingham
United Kingdom
B9 5SS

Sponsor information

Organisation

Department of Health (UK)

ROR

https://ror.org/03sbpja79

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research (NIHR) (UK) - Policy Research Program (PRP) (ref: 0190014)

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	01/04/2010		Yes	No
Protocol article	protocol	03/10/2007		Yes	No