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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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
EMMS

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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet

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 measure
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

Secondary outcome measures
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

Overall study start date
01/10/2005

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
12,000

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
England

United Kingdom

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

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Skipton House
80 London Road
London
United Kingdom
SE1 6LH

Sponsor type
Government

Website
http://www.dh.gov.uk/en/index.htm

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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