Comparison of 3M BacLite MRSA detection methods with conventional MRSA culture methods.

Published: 18-12-2007
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To evaluate whether the 3M BacLIte system has a comparable sensitivity and specificity with the hitherto used conventional culture protocols

Ethical review	Approved WMO
Status	Will not start
Health condition type	Bacterial infectious disorders
Study type	Observational non invasive

Summary

ID

NL-OMON32117

Source
ToetsingOnline

Brief title
Validation 3M BacLite

Condition

- Bacterial infectious disorders

Synonym
MRSA carriage

Research involving
Human

Sponsors and support

Primary sponsor: Stichting PAMM
Source(s) of monetary or material Support: 3M Nederland BV,Eigen middelden Stichting PAMM;Laboratorium Medische Microbiologie te Veldhoven. Apparatuur en reagentia BacLite worden beschikbaar gesteld door 3M Nederland BV

Intervention

Keyword: culture, MRSA

Outcome measures

Primary outcome

sensitivity, specificity and positive and negative predictive value of the 3M

BacLite system compared to conventional cultures methods.

Secondary outcome

not applicable

Study description

Background summary

In the Netherlands the prevalence of MRSA in clinical isolates of Staphylococcus aureus is with 1.0%, one of the lowest in Europe (1). This low prevalence is best explained by the national *search and destroy* policy, that asks for admission screening and isolation of all patients that are at risk of MRSA carriage (www.wip.nl) . The *at-risk* patients mainly consisted of patients who have been admitted to and/or treated in foreign hospitals and people in contact with live pigs and veal calves. The MRSA carriage rates in these groups are 3.5-5% (3) and 26% respectively (4) . Isolation of these patients is maintained until the results of screening cultures (nose, throat and perineal region, and if applicable wounds, urine and sputum) is known. MRSA screening cultures that are performed in accordance with the national Dutch guideline (www.nvmm.nl) take between 3-7 days, whereas the 3M BacLite system takes 5 hrs- 24 hrs to gain a result. In this study two conventional culture methods are compared with the 3M BacLite system. One method uses a 48 hr incubation in a selective broth, with subsequent subculturing on blood agar. This is the method currently described by the Dutch Medical Microbiology society. The second method uses a 24 hr non-selective broth with subculturing on a commercial chromogenic MRSA agar (MRSA hromID, bioMerieux). These methods are compared with the 3M BacLite, which is a rapid culture system using a 5 hr semi-selective broth enrichment with subsequent extraction of S. aureus with magnetic beads. After extraction and lysis of the bacteria, adenylaat kinase release is monitored.
Since the majority of patients that have to be isolated and screened is eventually MRSA negative, having quick and reliable results, decreases the

number of isolation days in the hospital. This is both in the interest of the hospital and the patient.

Study objective

To evaluate whether the 3M BacLlte system has a comparable sensitivity and specificity with the hitherto used conventional culture protocols

Study design

Cohort

Study burden and risks

The burden consists of taking extra set of screening cultures (swabs) from nose/throat/perineal region and if applicable wounds. There are no risks associated with this procedure. There is no benefit during the study for the participating patients.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Indication for screening and isolation according to WIP guideline *MRSA* and/or known MRSA carrier.

Exclusion criteria

Not able to give informed consent

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Will not start
Start date (anticipated):	01-11-2007
Enrollment:	425
Type:	Anticipated

Ethics review

Approved WMO

Date:	18-12-2007

Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL20367.060.07