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Reducing transmission of methicillin-resistant Staphylococcus aureus in a surgical ward of a resource-limited hospital in Indonesia: An intervention study

Submission date
27/05/2017

Recruitment status
No longer recruiting

Registration date
26/07/2017

Overall study status
Completed

Last Edited
05/09/2023

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Staphylococcus aureus is a bacterium that is carried by 30% of humans, mainly in the nose and on the skin. Humans and S. aureus generally co-exist well. Sometimes, S. aureus may cause an infection, such as wound infections after surgery. These infections can be treated with antibiotics. During the last decades, the amount of S. aureus that is resistant to many of the antibiotics used to treat infections, the so-called MRSA (methicillin-resistant S. aureus) has increased, both in the community and hospital setting. Although the frequency varies among regions and countries, MRSA has been found worldwide. The burden of disease, however, seems to be higher in developing countries compared to developed countries. Effective actions to prevent or reduce the spread of MRSA within healthcare facilities have been conducted in several developed countries. However, the preventive actions have not been implemented in healthcare settings in resource-limited countries, since other healthcare issues such as HIV/AIDS, malaria, and tuberculosis are commonly prioritized on the public health care agendas in these countries. Active actions to prevent MRSA transmission (spreading) could reduce the amount of MRSA infections in developing countries such as Indonesia. The aim of this study is to design feasible actions to prevent further transmission of MRSA in the surgery ward of the Dr. Saiful Anwar Hospital in Malang, Indonesia, and to measure the effect of introducing these preventive measures on the transmission and acquisition of MRSA.

Who can participate?
All patients admitted to the study rooms in the surgery ward.

What does the study involve?
Participating patients and healthcare workers are screened for MRSA. Patients are screened for MRSA at admission to the hospital, day five of hospitalization, and at discharge. This is done through swabs of the nose, throat and open skin areas. Participating healthcare workers are screened twice through swabs of the nose, throat and skin lesions. Preventative measures are introduced to the hospital to reduce the level of MRSA transmission. These include hand

washing education, treating MRSA positive participants with a decolonization therapy (a therapy body wash and nasal ointment to get rid of any MRSA) and cleaning the surgery ward twice. Participants are rescreened again for MRSA to see if the MRSA rates have been reduced.

What are the possible benefits and risks of participating?
Participants may benefit from being identified that they carry MRSA and being offered eradication therapy to prevent infections. This can also decrease the risk of transmission. Some risks involved in the study include reactions to the swabs (sneezing, gaggin, irritation) as well as sensitivity to the decolonization therapy.

Where is the study run from?
This study is being run by Erasmus University Medical Center (Netherlands) and takes place in the Dr Saiful Anwar hospital (Indonesia)

When is the study starting and how long is it expected to run for?
January 2012 to April 2017

Who is funding the study?
Erasmus University Medical Center (Netherlands)

Who is the main contact?
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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

MRSA2012/FKUB-RSSA

Study information

Scientific Title
Intervention study for the containment of methicillin-resistant Staphylococcus aureus (MRSA) in a surgical ward of a low resource hospital in Indonesia

Study objectives
The aim of this study is to design feasible actions to prevent further transmission of MRSA in the surgery ward of the Dr. Saiful Anwar Hospital in Malang, Indonesia, and to measure the effect of introducing these preventive measures on the transmission and acquisition of MRSA.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethics Committee of Dr. Saiful Anwar hospital, Malang, Indonesia, 09/05/2012, ref: 129 /EC/KEPK-JK/05/2012

Study design
Interventional non randomised single-centre cohort study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Interventions
This study consists of three phases and takes place over a period of 24 weeks.

Phase 1: Pre-intervention phase (ten weeks)
During the first phase screening of patients, health-care workers and the environment are screened to monitor the epidemiology of S. aureus on the surgery ward. Screening of patient is conducted three times: at admission, at day five of hospitalisation, and at discharge by culturing swabs of anterior nares, throat, and open skin lesion (if present). When a patient is still

hospitalised at the end of the phase 1, they are screened again at the end of this phase. Screening of healthcare workers and the environment is conducted twice: at the beginning and at the end of this phase. Also, the rate of compliance of the healthcare workers with the World Health Organization (WHO) guidelines for hand hygiene is measured. The compliance of the healthcare workers with the guidelines from the WHO for hand hygiene is observed repeatedly throughout the study. During these observations the observers (2 Indonesian students and 2 Dutch students, all trained) use the five moments of hand hygiene as defined by the WHO and counted the times the healthcare workers performed proper hand hygiene during these moments as they occurred. The five moments of hand hygiene according to the WHO are:
1. Before touching a patient.
2. Before a clean or aseptic procedure.
3. After body fluid exposure risk.
4. After touching a patient.
5. After touching patient surroundings (for example after touching the bed or table of a patient).
The observation is conducted two to three times per day to get enough observation moments.

Phase 2: Intervention phase (four weeks):
During this phase a bundle of preventive measures will be introduced in the ward in order to lower the acquisition rate of MRSA among patients and healthcare workers and to reduce the level of contamination of the environment with MRSA. Also, an educational program will be undertaken to improve compliance of the nursing staff with hand hygiene guidelines.

The bundle of preventive actions consists of:
1. An hand-hygiene educational program, as part of the preventive measures, was undertaken to improve the compliance of healthcare workers with the hand hygiene guideline and included weekly presentations, distribution of information sheets and leaflets, and hanging large posters in the ward. In addition, we installed a bottle of 500 ml chlorhexidine-containing hand glycerin alcohol 0.5% at each bedside, and teaching the healthcare workes about proper hand hygiene according to WHO guideline
2. Cohorting all MRSA-positive patients behind a screen
3. Treating all MRSA-positive patients and healthcare workers with a decolonization therapy consisting of mupirocin dermatological cream 2% (Bactoderm cream, PT. Ikapharmindo Putramas, Indonesia) to both nares twice daily for five days plus chlorhexidine medicated soap 4% (Hibiscrub, Astra Zeneca) for 7 days. Patients and healthcare workers who carried MRSA in their throat were offered trimethoprim/sulfamethoxazole oral therapy 960 mg 2 twice daily
4. Cleaning and disinfecting the environment of the surgery ward twice, once at the beginning and once at the end of this phase using sodium hypochlorite 0.05% (for surfaces) and alcohol 70% (for instruments)

During this period the screening of MRSA is continued for patients. Healthcare workers and the environment are screened once at the beginning of this phase. When a patient is still hospitalized at the end of phase 2, he/she will be screened again at the end of this phase. Hand hygiene compliance will not be measured during this phase, since the researchers will be actively involved in instructing the healthcare workers to perform proper hand hygiene at the appropriate times.

Phase 3: Post-intervention phase (ten weeks):
During the last phase the epidemiology of S. aureus and compliance to hand hygiene guidelines in the surgery ward is monitored as described for Phase 1 in order to observe the effects of the implemented preventive measures.

During the study period the methicillin-resistant S. aureus (MRSA) and methicillin-sensitive S. aureus (MSSA)-acquisition rate among patients, the number of MRSA and MSSA positive healthcare workers, and the level of contamination of the environment with MRSA or MSSA are measured

Intervention Type
Mixed

Primary outcome measure
MRSA acquisition rate is measured by dividing the number of acquisition events of MRSA by the number of patient-days at risk in 1000 patient days.

Secondary outcome measures
1. Compliance rate for hand hygiene is assessed as the percentage of correct hand hygiene actions undertaken on moments when hand hygiene was considered necessary according to the WHO “five moments" at the pre-intervention phase and post-intervention phase.
2. Environmental contamination rate of MRSA is assessed as the percentage of environmental samples showing MRSA positive cultures on two screening moments in both the pre-intervention phase and post-intervention phase.

Overall study start date
20/01/2012

Completion date
23/04/2017

Eligibility

Key inclusion criteria
1. All patients admitted to the study rooms in surgery ward
2. Patients with complete culture sets, i.e. nose and throat swab taken on admission and either at day-5 hospitalization or at discharge (or both)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
450 patients per each phase

Total final enrolment
1120

Key exclusion criteria

Patients leaving the room within 48 hours of admission.

Date of first enrolment
03/07/2012

Date of final enrolment
22/08/2013

Locations

Countries of recruitment
Indonesia

Study participating centre
Dr. Saiful Anwar Hospital
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Sponsor information

Organisation
Erasmus University Medical Center

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/018906e22

Funder(s)

Funder type

Hospital/treatment centre

Funder Name
Erasmus University Medical Center

Results and Publications

Publication and dissemination plan
Planned to submit the manuscript to Infection Control and Hospital Epidemiology in October 2017.

Intention to publish date
31/10/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analyzed during the current study are/will be available upon request from dewi_santosa@yahoo.com

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		03/12/2019	05/09/2023	Yes	No