Turning the tide of antimicrobial resistance in intensive care units in Indonesia

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26918

Source Nationaal Trial Register

Health condition

Antimicrobial resistance, Intensive care

Sponsors and support

Primary sponsor: 1.Faculty of Medicine Universitas Indonesia / Dr Cipto Mangunkusumo Hospital Jakarta, Indonesia
2. Erasmus MC Rotterdam, The Netherlands
Source(s) of monetary or material Support: Directorate General of Higher Education (DGHE) of Indonesia

Intervention

Outcome measures

Primary outcome

The number of patients who acquire carriage or infection with A. baumannii with reduced susceptibility to carbapenems, P. aeruginosa with reduced susceptibility to carbapenems, or K. pneumoniae with reduced susceptibility to carbapenems per 100 patient-days at risk in the

ICU.

An acquisition is defined as a screening culture (throat or rectum) or clinical culture with a first detection of either A. baumannii, P. aeruginosa, or K. pneumoniae, all with reduced susceptibility to a carbapenem, that was not yet present on admission or in the first 48 hours of admission. Thus, for each patient, a maximum of three new acquisition events may occur.

Secondary outcome

Measures include quantity and quality of antibiotic usage, the in-ICU crude mortality rate, the hand hygiene compliance of health care workers, and environmental contamination of the above mentioned Gram-negative bacteria with reduced susceptibility to carbapanems.

Study description

Background summary

Antimicrobial resistance of bacteria has emerged worldwide as a major health care problem, but particularly emerges in and affects low-resource countries. It is in the interest of global health that antimicrobial resistance is addressed and combated with a focus on interventions in developing countries. Intensive care units (ICUs) are a hot-spot for the emergence of extremely-drug resistant Gram-negative bacteria. In a pilot study in the ICU of the Dr. Cipto Mangunkusumo Hospital in Jakarta, Indonesia, it was shown that multidrug-resistant (MDR) Pseudomonas aeruginosa, MDR Acinetobacter baumannii, and carbapenem-resistant Klebsiella pneumoniae were prevalent. Containment strategies such as those recommended by the Centers for Disease Control and Prevention (CDC) are, however, difficult to apply because of constrained budgets that demand prioritisation. In our research project we will implement a set of inexpensive interventions on a ICU in Indonesia, and monitor the effect of these interventions in a before-and-after study with a baseline period of 10 months (phase I), a period for the implementation of the bundle of interventions of 2

months (phase II), and an after period of 10 months (phase III). The target microorganisms will be P. aeruginosa, A. baumannii, and K. pneumoniae, all with reduced susceptibility to carbapenem antibiotics. The primary outcome will be the number of patients who acquire carriage or infection with one of the three target microorganisms per 100 patient-days at risk in the ICU.

Our study will result in a scientifically based, efficient strategy to limit the emergence of resistance bacteria in Indonesian ICUs. This programme could be the starting point for a nationwide action in Indonesian ICUs. The results of our study will also be useful for ICUs in other low-resource countries.

Study objective

A bundle of inexpensive interventions can reduce the emergence and spread of carbapenem

non-susceptible Gram-negative bacteria in a low-resource ICU.

Study design

Stool or rectum samples and throat samples will be obtained from patients on the ICU on admission, then weekly until discharge from the ICU and on discharge.

Intervention

1.Contact Isolation Precautions for patients colonized or infected with a carbapenem nonsusceptible Gram-negative bacterium (Pseudomonas aeruginosa, Klebsiella pneumoniae, or Acinetobacter baumannii).

2.Cohorting patients with a carbapenem non-susceptible Gram-negative bacterium (Pseudomonas aeruginosa, Klebsiella pneumoniae, or Acinetobacter baumannii).

3.Source control, for all included patients:

a. Bathing: once daily with chlorhexidine 2%

b. Oral hygiene for intubated patient \Rightarrow 4 times daily --> 2% solutions of chlorhexidine

- 4. Environmental cleaning
- 5. Antibiotic Stewardship

6. Multifaceted program to improve hand hygiene compliance (including education, feedback, reminders, interviews and the use of role models).

Contacts

Public Erasmus MC

Juliette Severin Rotterdam The Netherlands 010-7033510 **Scientific** Erasmus MC

Juliette Severin Rotterdam

Eligibility criteria

Inclusion criteria

All adult patients (age \geq 18 years old) admitted to the intensive care unit of Dr Cipto Mangunkusumo Hospital in Jakarta, Indonesia.

Exclusion criteria

Patients who are discharged within 48 hours from the intensive care unit.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-04-2013
Enrollment:	550
Туре:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion Date: Application type:

22-12-2015 First submission

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

NTR-new NL5424 NTR-old NTR5541 The Ethics Committee of the Faculty of Medicine, Universitas Indonesia : Other 561/PT02.FK/ETIK/2012

Study results

Summary results

The study is published in the journal 'Antimicrobial Resistance and Infection Control'. DOI 10.1186/s13756-017-0296-7.