

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

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A bundle of inexpensive interventions can reduce the emergence and spread of carbapenem non-susceptible Gram-negative bacteria in a low-resource ICU.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26918

Bron

Nationaal Trial Register

Aandoening

Antimicrobial resistance, Intensive care

Ondersteuning

Primaire sponsor: 1.Faculty of Medicine Universitas Indonesia / Dr Cipto Mangunkusumo Hospital Jakarta, Indonesia

2. Erasmus MC Rotterdam, The Netherlands

Overige ondersteuning: Directorate General of Higher Education (DGHE) of Indonesia

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

A bundle of inexpensive interventions can reduce the emergence and spread of carbapenem non-susceptible Gram-negative bacteria in a low-resource ICU.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

1. Contact Isolation Precautions for patients colonized or infected with a carbapenem non-susceptible 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 → 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).

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-04-2013
Aantal proefpersonen:	550
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum: 22-12-2015

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten

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