

Risk factors for multi-drug resistant *P. aeruginosa*

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The aim of this study is to analyze the risk-factors associated with acquiring VIM-2 positive *P. aeruginosa*, among patients admitted to the Erasmus University Medical Center since the first recorded case in 2003. Secondary aims: 1.To...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON24496

Bron

Nationaal Trial Register

Aandoening

VIM-2 positive *Pseudomonas aeruginosa*
Healthcare-related/Gezondheidszorg gerelateerd
Multi-drug resistant/multiresistent
Risk factors/Risicofactoren

Ondersteuning

Primaire sponsor: Not applicable

Overige ondersteuning: Not applicable

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

VIM-2 positive culture of *P. aeruginosa* (infection or colonization)

Absence of VIM-2 positive *P. aeruginosa* (infection or colonization)/culture of *P. aeruginosa* (infection or colonization)

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Since continuous outbreaks of VIM-2 positive *P. aeruginosa* occur in the Erasmus MC, additional research is needed to expand our knowledge of VIM-2 positive *P. aeruginosa* transmission and to identify risk factors applicable to the Erasmus MC, so we can implement targeted prevention strategies in order to stop the outbreaks.

Objective: The main aim of this study is to analyze the risk-factors associated with acquiring VIM-2 positive *P. aeruginosa*, among patients admitted to the Erasmus University Medical Center since the first recorded case in 2003. The secondary aim is to investigate whether there is a difference in risk-factors between ICU and non-ICU patients in the Erasmus Medical Center. Also, to investigate whether Diversilab types are associated with specific risk-factors.

Study design: Case-control study (observational)

Study population: The population consist of adult patients (≥ 18 years) admitted to the Erasmus MC

Main study parameters/endpoints: The main outcomes are: VIM-2 positive culture after 48 hours after admittance in the Erasmus MC (Colonization and infection) and VIM-2 negative colonization and infection

Doel van het onderzoek

The aim of this study is to analyze the risk-factors associated with acquiring VIM-2 positive *P. aeruginosa*, among patients admitted to the Erasmus University Medical Center since the first recorded case in 2003.

Secondary aims:

1. To investigate whether there is a difference in risk-factors between ICU and non-ICU patients in the Erasmus Medical Center. If that is the case, what are those differences?

2. To investigate whether Diversilab types are associated with specific risk-factors. (E.g. Diversilab types can be associated with medical materials used on various wards (ICU/non-ICU); prior carbapenem use; patient characteristics like age and sex etc.). (For example, males over the age of 50 have a higher odds (x) of acquiring Diversilab type B... when admitted on the ICU.. when having a urinary catheter and so on).

Onderzoeksopzet

The time period in which cases are identified ranges from August 2003 till April 2015.

Onderzoeksproduct en/of interventie

Not applicable

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- VIM-2 positive culture after 48 hours after admittance in the Erasmus University Medical

Center.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Children, because they are admitted at the Sophia Children's Hospital and are separated from the Erasmus MC facilities. To our knowledge, there is no evidential cross-over potential of VIM-2 positive *P. aeruginosa* to the adult-care facilities.
- The outbreak resulting from Endoscopic Retrograde Cholangiopancreatography (ERCP). This outbreak has a known cause and is therefore reported and investigated separately (21).
- Patients only admitted at the Erasmus MC Cancer Institute . These patients are cared for in a separate building of the Erasmus MC and are therefore not be included in this study.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	25-03-2015
Aantal proefpersonen:	140
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum: 23-03-2015

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	NL4874
NTR-old	NTR5145
Ander register	: MEC-2015-240

Resultaten

Samenvatting resultaten

Voor in 't holt AF, Severin JA, Lesaffre EM and Vos MC. A systematic review and meta-analyses show that carbapenem use and medical devices are the leading risk factors for carbapenem-resistant *Pseudomonas aeruginosa*. Antimicrob Agents Chemother 2014;58:2626-37.