Risk factors for multi-drug resistant P. aeruginosa

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24496

Source
NTR

Health condition

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

Sponsors and support

Primary sponsor: Not applicable
Source(s) of monetary or material Support: Not apllicable

Intervention

Outcome measures

Primary outcome

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

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

Secondary outcome

Not appliacble

Study description

Background summary

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 (>=18years) 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

Study objective

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).

Study design

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

Intervention

Not applicable

Contacts

Public
Erasmus Medisch Centrum Rotterdam - Department of Medical Microbiology & Infectious diseases

Margreet C. Vos
Wytemaweg 80, Room Na-901k

Rotterdam 3015 CN
The Netherlands
0107033510
Scientific
Erasmus Medisch Centrum Rotterdam - Department of Medical Microbiology & Infectious diseases

Margreet C. Vos
Wytemaweg 80, Room Na-901k

Rotterdam 3015 CN
The Netherlands
0107033510

Eligibility criteria

Inclusion criteria

• VIM-2 positive culture after 48 hours after admittance in the Erasmus University Medidcal Center.

Exclusion criteria

• 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.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-03-2015
Enrollment:	140
Type:	Actual

Ethics review

Positive opinion

Date:	23-03-2015

Application type: 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	NL4874
NTR-old	NTR5145
Other	: MEC-2015-240

Study results

Summary results

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.