

Single- or Multiple-occupancy room isolation of patients colonised with ESBL-producing Enterobacteriaceae.

Gepubliceerd: 04-03-2011 Laatste bijgewerkt: 13-12-2022

The primary objective of this study is to demonstrate that contact isolation of patients colonised with ESBL-producing Enterobacteriaceae in a multiple-occupancy room is not inferior to contact isolation in a single-occupancy room with respect to...

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

Samenvatting

ID

NL-OMON20768

Bron

NTR

Verkorte titel

SoM

Aandoening

Antimicrobial resistance

Infection prevention

Nosocomial infection

Ondersteuning

Primaire sponsor: VU medical center

Overige ondersteuning: ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The transmission rate of ESBL-producing Enterobacteriaceae, i.e. the proportion of index patients in which transmission of ESBL-producing Enterobacteriaceae to a ward mate occurs.

Toelichting onderzoek

Achtergrond van het onderzoek

Objectives:

The primary objective of this study is to demonstrate that contact isolation of patients colonised with ESBL-producing Enterobacteriaceae in a multiple-occupancy room is not inferior to contact isolation in a single-occupancy room with respect to the horizontal transmission of ESBL-producing Enterobacteriaceae to other hospitalised patients.

The secondary objectives pertain not only to the comparison of the two isolation strategies, but also to the prevalence and follow-up data, the clinical culture data and the development of microbiological methods.

Study design:

This study is designed as a multicentre, cluster-randomised, cross-over study.

Study population:

1. Participating centres: University, teaching or general hospitals;
2. Index patients: Patients with an age ≥ 18 years, that are hospitalised on a non-ICU, non-hemato-oncology, non-transplantation ward, and are colonised or infected with ESBL-producing Enterobacteriaceae;
3. Ward mates: Patients that are hospitalised on the index ward on day 7 (+/-2) after inclusion of the index patient.

Intervention:

2 - Single- or Multiple-occupancy room isolation of patients colonised with ESBL-pro ... 4-05-2025

Two isolation strategies will be compared in this study:

1. Contact isolation in a single-occupancy room;
2. Contact isolation in a multiple-occupancy room.

The two isolation strategies will be performed in two consecutive periods, where the order is randomly assigned to the participating centres.

Primary study endpoint:

The primary endpoint of this study is the transmission rate of ESBL-producing Enterobacteriaceae.

Doel van het onderzoek

The primary objective of this study is to demonstrate that contact isolation of patients colonised with ESBL-producing Enterobacteriaceae in a multiple-occupancy room is not inferior to contact isolation in a single-occupancy room with respect to the horizontal transmission of ESBL-producing Enterobacteriaceae to other hospitalised patients.

Onderzoeksopzet

1. 7 days: Prevalence of colonisation with ESBL-producing Enterobacteriaceae, including presence of resistance genes;
2. Admission until discharge: Infection with ESBL-producing Enterobacteriaceae;
3. 28 days: All-cause mortality;
4. 6 months: All-cause mortality.

Onderzoeksproduct en/of interventie

1. Contact isolation on a single-occupancy room;
2. Contact isolation on a multiple-occupancy room.

Contactpersonen

Publiek

Amphia Hospital, location Molengracht / PObox 90158
M.F.Q. Kluytmans - Bergh, van den
Breda 4800 RK
The Netherlands
+31 (0)76 5953015

Wetenschappelijk

Amphia Hospital, location Molengracht / PObox 90158
M.F.Q. Kluytmans - Bergh, van den
Breda 4800 RK
The Netherlands
+31 (0)76 5953015

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients that are hospitalised on a non-ICU, non-hemato-oncology, non-transplantation ward, and are colonised or infected with ESBL-producing Enterobacteriaceae.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Patients with an age of less than 18 years;
2. Patients who refuse or are unable to give permission for using patient-specific data;
3. Patients that are known to be colonised or infected with a microorganism that requires isolation in a single room, e.g. highly resistant *Acinetobacter* spp., highly resistant *Streptococcus pneumoniae*, highly resistant *Enterococcus faecium*, MRSA, and (multiresistant) *Mycobacterium tuberculosis*;
4. Patients that are colonised or infected with ESBL-producing Enterobacteriaceae of the same* species and with the same antibiogram as that of an isolate that has been detected previously in clinical cultures of previously included index patients or ward mates that are at that moment still hospitalised on the same ward.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	01-02-2011
Aantal proefpersonen:	592
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Toelichting

IPD are available from the first author on reasonable request

Ethische beoordeling

Positief advies	
Datum:	04-03-2011
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	NL2671
NTR-old	NTR2799
Ander register	METC St. Elisabeth Hospital : METC/jv/2010.234
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

[https://www.thelancet.com/journals/laninf/article/PIIS1473-3099\(19\)30262-2/fulltext](https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(19)30262-2/fulltext)