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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20768

Source
NTR

Brief title
SoM

Health condition

Antimicrobial resistance
Infection prevention
Nosocomial infection

Sponsors and support

Primary sponsor: VU medical center
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

1. The transmission rate of mobile genetic elements harbouring resistance genes that encode for ESBL, i.e. the proportion of index patients in which transmission of mobile genetic elements to a ward mate occurs;

2. The occurrence of ESBL-producing Enterobacteriaceae in clinical cultures from hospitalised patients;

3. The prevalence of colonisation with ESBL-producing Enterobacteriaceae in hospitalised patients;

4. All-cause mortality at 28 days and after 6 months.

Study description

Background summary

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:

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.

Study objective

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.

Study design

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.

Intervention

1. Contact isolation on a single-occupancy room;

2. Contact isolation on a multiple-occupancy room.

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-02-2011
Enrollment:	592
Type:	Actual

IPD sharing statement

Plan to share IPD: Yes

Plan description
IPD are available from the first author on reasonable request

Ethics review

Positive opinion

Date:	04-03-2011
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	NL2671
NTR-old	NTR2799
Other	METC St. Elisabeth Hospital : METC/jv/2010.234
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(19)30262-2/fulltext