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Impact of contact precautions for preventing bacterial (Pseudomonas aeruginosa) infections in intensive care units

Submission date
17/06/2020

Recruitment status
No longer recruiting

Registration date
19/06/2020

Overall study status
Completed

Last Edited
03/11/2020

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
In intensive care units (ICUs), the bacteria Pseudomonas aeruginosa is a major cause of healthcare-associated infections. The issue of physical contact precautions as contributory factors for reducing Pseudomonas aeruginosa infections in ICUs remains questioned.
We aimed to evaluate the benefit of the addition of contact precautions to standard precautions in P. aeruginosa-positive patients for reducing the risk of ICU-acquired P. aeruginosa infections.

Who can participate?
Adult (older than 15-year old) patients admitted for more than 24 hours in ICU

What does the study involve?
Ten French ICUs were randomly assigned to take additional precautions or standard precautions for 6 months, followed by a 3 month break, followed by 6 months using the other precautions to the first 6 months.

What are the possible benefits and risks of participating?
Minimal risk of adverse events

Where is the study run from?
University Hospital of Besançon (France)

When is the study starting and how long is it expected to run for?
May 2011 to December 2014

Who is funding the study?
This work was supported by the French Ministry of Health (PHRC national 2011)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
2011-A01013-38

Study information

Scientific Title
Do contact precautions reduce the incidence of ICU-acquired Pseudomonas aeruginosa infections? The DPCPYO cluster-randomised crossover trial

Acronym
DPCPYO

Study objectives
To evaluate the benefits of contact precautions over standard precautions for reducing the incidence of ICU-acquired Pseudomonas aeruginosa infections

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 16/05/2011, The human research ethics committee of the Besançon University Hospital (Le comité de protection des personnes (CPP) - EST II, 2 Place Saint-Jacques, Besançon, France; +33 3 81 21 93 12; cpp@chu-besancon.fr), ref: 2011-A01013-38

Study design

Multicentre cluster-randomised crossover trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Prevention of ICU-acquired Pseudomonas aeruginosa infections

Interventions
Ten French ICUs were randomly assigned (1:1) to sequence 0-1 (6-month control period /3-month wash-out period/6-month intervention period) or sequence 1-0 (6-month intervention period/3-month wash-out period/6-month control period).

Intervention period (the addition of contact precautions to standard precautions) vs control period (standard precautions) for Pseudomonas aeruginosa-positive patients with a surveillance screening programme.

The interventions (contact precautions) are the systematic implementation of the following measures: placing in single room or cohorting, signalling on the door, wearing gown, appropriate hand hygiene at the exit of the patient room and prescribing of contact precautions in the medical record.

Intervention Type
Behavioural

Primary outcome(s)
Rate of ICU-acquired Pseudomonas aeruginosa infections measured using routine diagnostic samples (blood, bronchoalveolar lavage, urine…) with routine clinical surveillance of patients that remained unchanged throughout the study period. Patients were screened for P. aeruginosa carriage (throat swab/tracheal aspirate and rectal swab) upon ICU admission (≤ 48 h) and once a week thereafter.

Key secondary outcome(s))
1. Rate of Pseudomonas aeruginosa acquisition (acquired infection and/or colonisation) measured as above.
2. Clonal relatedness of P. aeruginosa isolates measured using the Simpson diversity index and transmission index of Pseudomonas aeruginosa isolates within ICUs throughout the study.

Completion date
31/12/2014

Eligibility

Key inclusion criteria
Adult (> 15-year old patients) admitted for more than 24 hours in ICU

Participant type(s)

Patient

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Total final enrolment
3283

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/01/2012

Date of final enrolment
26/06/2014

Locations

Countries of recruitment
France

Study participating centre
University Hospital of Besançon - Jean MINJOZ
3 Bd Fleming
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Sponsor information

Organisation
Centre Hospitalier Universitaire de Besançon

ROR
https://ror.org/0084te143

Funder(s)

Funder type
Government

Funder Name
French Ministry of Health - PHRC national 2011

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during the current study will be available after de-identification, from 6 months and until 24 months after the article publication, upon request to Dr Houssein Gbaguidi-Haore (hhgbaguidihaore@chu-besancon.fr) by providing a research project proposal and after signing a data access agreement.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	02/11/2020	03/11/2020	Yes	No