

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

Submission date 17/06/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 19/06/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 03/11/2020	Condition category Infections and Infestations	<input type="checkbox"/> 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?

Dr Houssein Gbaguidi-Haore
hhgbaguidihaore@chu-besancon.fr

Contact information

Type(s)

Scientific

Contact name

Dr Houssein Gbaguidi-Haore

ORCID ID

<http://orcid.org/0000-0002-1825-9358>

Contact details

3 Bd Fleming

Besançon

France

25030

+33 3 70 63 21 37

hhgbaguidihaore@chu-besancon.fr

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Secondary study design

Cluster-randomised crossover trial

Study setting(s)

Hospital

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

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.

Secondary outcome measures

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.

Overall study start date

16/05/2011

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

Age group

Mixed

Sex

Both

Target number of participants

5000 patients from 10 ICUs from 6 university hospitals

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

Besançon
France
25030

Sponsor information

Organisation

Centre Hospitalier Universitaire de Besançon

Sponsor details

2 Place Saint-Jacques
Besançon
France
25030
+33 3 81 66 81 66
recherche@chu-besancon.fr

Sponsor type

Hospital/treatment centre

Website

<http://www.chu-besancon.fr/>

ROR

<https://ror.org/0084te143>

Funder(s)

Funder type

Government

Funder Name

French Ministry of Health - PHRC national 2011

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

Intention to publish date

30/07/2020

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