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The PROHIBIT study: reducing patients' risk of developing a central venous catheter infection by improving catheter insertion and health care workers' hand hygiene compliance in European Intensive Care Units

Submission date
10/09/2015

Recruitment status
No longer recruiting

Registration date
15/09/2015

Overall study status
Completed

Last Edited
18/01/2019

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
A central venous catheter (CVC) is a long, thin tube that is inserted into the major vein in the neck (jugular vein), chest (subclavian vein or axillary vein) or groin (femoral vein). CVC's are considered to be one of the best ways to give long-term drug treatment, such as chemotherapy. The use of CVC's has increased considerably in recent years and catheter-related bloodstream infections (CR-BSI) have become a recurrent complication. These infections can cause seriously ill patients with CVC's to become even more ill or even die. It is thought that the amount of CR-BSI' s in hospitals is related to the way the catheters are inserted and cared for, as well as hand hygiene practices. The aim of this study is to find out whether applying new hand hygiene and CVC insertion and care programmes in hospitals can help to reduce the amount of CR-BSI's.

Who can participate?
Adult patients with a CVC inserted in the hospital, on an ICU ward of a participating hospital.

What does the study involve?
In this study, each of the hospitals taking part is randomly allocated to take the different interventions (programmes) at different times. This means, that each hospital receives all of the different interventions though the course of the study. In a random order, each hospital implements their standard practices for CVC insertion and hand hygiene, the hand hygiene improvement programme, the CVC insertion and care programme or both of these programmes. Throughout the study, the number of CR-BSI's are recorded every three months.

What are the possible benefits and risks of participating?
Participants are expected to benefit because improving hand hygiene practices and CVC insertion techniques, the chances of a CR-BSI will be lower. There are no risks of participating in the study.

Where is the study run from?
Fifteen hospitals in Europe.

When is the study starting and how long is it expected to run for?
December 2008 to June 2013

Who is funding the study?
Seventh Framework Programme (Belgium)

Who is the main contact?
Ms Tjallie van der Kooi
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Study website
https://plone.unige.ch/prohibit/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The PROHIBIT (PRevention Of Hospital Infections By Intervention and Training) intervention study: a randomized multi-centre study in Intensive Care Units in Europe to reduce central venous catheter-related bloodstream infections (CRBSIs) by improving hand hygiene (HH) and central venous catheter (CVC) insertion and care, measuring both CRBSI incidence density and HH and CVC insertion compliance

Acronym
PROHIBIT WP5

Study objectives
To test the efficacy of a hand hygiene programme (World Health Organization (WHO)) and a CVC insertion and care programme (University Hospitals of Geneva), or both in improving prevention of central venous catheter (CVC)-related bloodstream infections (CRBSI) in the heterogeneous European setting.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Medical Ethics Review Committee of the University Medical Centre of Utrecht (Netherlands) concluded that ethics approval was not required, because the interventions consisted of best practice quality of care and patients did not receive a particular treatment, the Medical Research Involving Human Subjects Act (WMO) did not apply.

Local Ethics Approvals:
1. Austria: Ethics Committee of the Medical University Vienna, 04/10/2011
2. Belgium: Medical Ethics Committee of the AZ Sint Lucas hospital, 14/02/2010
3. Greece: Scientific and Ethics Committee of the Evaggelismos General Hospital: 17/01/2011
4. Hungary: Bácks-Kiskun county teaching hospital: Research Ethics Committee of the Szeged University: 30/03/2011
5. Hungary: Research Ethics Committee of the Szent János hospital, Budapest:: , 21/7/2011
6. Ireland: Clinical Research Ethics Committee of Galway University Hospitals: , 02/11/2010
7. Ireland: Ethics and Medical Research Committee of the St. Vincent's Healthcare group, Dublin, 17/01/2011
8. Italy: Committee of Bio-ethics of the Riuniti hospital of Bergamo, 02/11/2010
9. Latvia: Clinical Research Ethics Committee of the Paul Stradins Clinical University Hospital, 01 /12/2010
10. Poland: Hospital of Silesia, Cieszyn: the Beskidzka Medical Doctors Association, 15/12/2011
11. Poland: Legal advisor of the John Paul II Regional Teaching Hospital, Kraków, 20/01/2011
12. Romania: Ethics Committee of the Institute for emergency cardiovascular diseases "Prof. C.C. Iliescu", 02/11/2010
13. Slovenia: Medical Ethics Committee of the Republic of Slovenia, 27/12/2010
14. Spain: Clinical Research Ethics Committee of the Vall d'Hebron University Hospital, 28/01 /2011

Study design
Multi-centre randomized controlled stepped-wedge design

Primary study design
Interventional

Secondary study design
Randomized controlled stepped-wedge design

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Catheter-related bloodstream infections

Interventions
The cluster-randomized stepped wedge design allowed all centres to implement the intervention and to account for time-related changes. The baseline period functions as control period. Hospitals were randomized to receive one of the interventions described below (HH, CVC or BOTH). After a baseline of six months the first randomization took place: per intervention one hospital was randomly selected to start. After three months the second randomization round took place. There were in total 5 randomization rounds.

Control phase: Local practices regarding CVC insertion and hand hygiene are used.

Intervention phase: One or both of the following interventions were implemented:

Multimodal hand hygiene (HH) improvement programme (WHO):
1. System and infrastructure for HH (e.g. availability of hand alcohol at the bedside)
2. Training and education of healthcare workers
3. Evaluation and feedback to healtcare workers and management
4. Reminders in the workspace
5. Institutional safety climate

CVC insertion and care programme based on the University of Geneva Hospitals (HUG) catheter project:
1. Work organization
2. Patient preparation
3. Skin antisepsis
4. Maximal sterile barrier precautions
5. Catheter fixation and dressing
6. After insertion: evaluation of ongoing need of the catheter

After the start of the intervention hospitals would receive quarterly feedback reports on their CRBSI rates, HH compliance and/or CVC insertion compliance, depending on the intervention. Hospitals recorded their implementational activities throughout the study.

Intervention Type
Behavioural

Primary outcome measure

Central venous catheter-related bloodstream infection (CRBSI) incidence density, measured as number of CRBSI per 1000 CVC days (CVC days of concurrent CVCdays were counted separately) every 3 months for 30 months.

Secondary outcome measures
1. Hand hygiene complianceias measured by direct observation using the well-known WHO “My five moments for hand hygiene” strategy (Sax et al, AJIC 2009) every 3 months for 30 months
2. Catheter insertion practice is measured by observing CVC insertions using a form based on the CRBSI prevention strategy of the University of Geneva Hospitals (Zingg et al, PloS one, 2014) every 3 months for 30 months

Overall study start date
02/12/2008

Completion date
30/06/2013

Eligibility

Key inclusion criteria
1. ICU patients with CVCs in place for at least 24 hours
2. Aged 16 years or over

Participant type(s)
Other

Age group
Adult

Sex
Both

Target number of participants
We aimed at including 15 centres: 5 per intervention, starting the intervention with 3 hospitals at the time, at 5 moments of time, 3 months apart. All hospitals collected data for 30 months. We expected that each hospital would contribute 10-15,000 CVC days per hospital per year.

Key exclusion criteria
1. CVCs inserted outside the hospital
2. CVCs removed at the same day

Date of first enrolment
01/01/2011

Date of final enrolment
30/06/2013

Locations

Countries of recruitment
Austria

Belgium

Belize

Greece

Hungary

Ireland

Italy

Latvia

Poland

Romania

Slovenia

Spain

Study participating centre
Allgemeines Krankenhaus Wien
Währinger Gürtel 18-20
Vienna 1
Austria
1090

Study participating centre
AZ Sint-Lucas Gent
Groenebriel 1
Ghent
Belgium
B-9000

Study participating centre
Evaggelismos Hospital
Ypsilandou str 45-47
Athens
Greece
10676

Study participating centre
Bács-Kiskun County Teaching Hospital
38. Nyíri street
Kecskemét
Hungary
6000

Study participating centre
Szent János Hospital
Gyali u. 2-6
Budapest
Hungary
1097

Study participating centre
University College Hospital Galway
Newcastle Road
Galway
Ireland
H91 YR71

Study participating centre
St. Vincent's University Hospital
Elm Park
Dublin
Ireland
4

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Bergamo
Italy
24127

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Pilsoņu str 13
Riga

Latvia
1002

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Prądnicka 80
Kraków
Poland
12 614 20 02

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43-400

Study participating centre
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Sponsor information

Organisation
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Sponsor type
Government

Website
http://www.rivm.nl/en

ROR
https://ror.org/01cesdt21

Funder(s)

Funder type
Not defined

Funder Name
Seventh Framework Programme

Alternative Name(s)
EC Seventh Framework Programme, European Commission Seventh Framework Programme, EU Seventh Framework Programme, European Union Seventh Framework Programme, FP7

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Publication and dissemination plan

Publication through a peer-reviewed journal.
Further dissemination via congresses (ECCMID 2014, ICPIC 2013 and ICPIC 2015).

Intention to publish date
31/12/2015

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2018	18/01/2019	Yes	No