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Prevention of peripheral venous catheter-related adverse events in hospital wards through the implementation of a multimodal intervention: PREBACP study

Submission date
06/03/2018

Recruitment status
No longer recruiting

Registration date
21/03/2018

Overall study status
Completed

Last Edited
31/08/2021

Condition category
Haematological Disorders

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

Plain English summary of protocol

Background and study aims
Venous catheters (small flexible tubes placed into veins) are the most commonly used invasive devices in hospitals worldwide. Patients can experience multiple problems during the insertion, maintenance and management of these devices. Catheter-related bloodstream infections (CRBSI) can have one of the worst impacts for patients and are potentially preventable. The rate of these infections associated with peripheral venous catheters (catheters in peripheral veins such as arms, legs, hands and feet) is between 0.1 - 0.5 per 1000 catheter per day. CRBSIs can prolong hospital stay between two and eleven days and cause mortality rate of up to 25%. Ensuring health professionals follow clinical practice guidelines when using peripheral venous catheters may help improve this care. This study aims to assess the effect of a combination of different strategies to help nurses follow these guidelines, and determine the effect of this on patients.

Who can participate?
Staff nurses and hospital patients aged over 18 years with peripheral venous catheter

What does the study involve?
Participants are randomized by ward to one of two groups. Those in the first group receive an intervention that lasts 12 months and uses several methods instructing new clinical practice guidelines. These include posters, technology, feedback, and dace to face training. Those in the control group continue with normal practice.

What are the possible benefits and risks of participating?
Participants involved in the study may help researchers to reduce catheter-related adverse events and minimize variability in healthcare. There are no direct risks associated with the study.

Where is the study run from?
Hospital Manacor (Spain)

When is the study starting and how long is it expected to run for?
September 2017 – February 2020

Who is funding the study?
College of Nurses of the Balearic Islands (Spain)

Who is the main contact?
Mr Ian Blanco-Mavillard (Public)
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Study website
https://proyectoprebacp.wixsite.com/prebacp

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PI2017-0192

Study information

Scientific Title

Prevention of peripheral venous catheter-related adverse events in hospital wards through the implementation of a multimodal intervention (PREBACP study): A multicentre cluster-randomised trial protocol.

Acronym
PREBACP

Study objectives
Current study hypothesis as of 25/06/2021:
Primary hypothesis:
The implementation of multimodal intervention will decrease the incidence of adverse events (Catheter-related bloodstream infections, dislodgement, extravasation, obstruction and phlebitis) associated with the use of peripheral venous catheters (PVCs) in adult hospital patients.

Secondary hypothesis:
1. Nursing practice outcomes: The fidelity of nurses to the recommendations for insertion and management of peripheral venous catheter within the Clinical Practice Guideline (CPG) in hospital wards receiving the intervention will demonstrate reduce healthcare variability, increase documented nursing records of peripheral vascular accesses (complete records) and increase extractions of the catheter tip culture from all PVC removed in patients experiencing adverse events.
2. Clinical outcomes: The fidelity of nurses to the recommendations for insertion and management of peripheral venous catheter within the CPG in hospital wards receiving the intervention, will reduce hospital length of stay (HLOS)
3. Health economic outcomes: The cost of implementation development will be compensated for the savings in length of stay hospital resulting from decreased to incidence of Catheter-related bloodstream infections.
4. Process evaluation: The contextual and individual factors on the utilization of knowledge in clinical practice decisions and impact on hospital ward processes and practice measured by Nursing Work Index (NWI) and Evidence-Based Practice Questionnaire (EBPQ).

Previous study hypothesis:
Primary hypothesis:
The implementation of multimodal intervention will decrease the incidence of adverse events (Catheter-related bloodstream infections, extravasation, obstruction and phlebitis) associated with the use of peripheral venous catheters (PVCs) in adult hospital patients.

Secondary hypothesis:
1. Nursing practice outcomes: The fidelity of nurses to the recommendations for insertion and management of peripheral venous catheter within the Clinical Practice Guideline (CPG) in hospital wards receiving the intervention will demonstrate reduce healthcare variability, increase documented nursing records of peripheral vascular accesses (complete records) and increase extractions of the catheter tip culture from all PVC removed in patients experiencing adverse events.
2. Clinical outcomes: The fidelity of nurses to the recommendations for insertion and management of peripheral venous catheter within the CPG in hospital wards receiving the intervention, will reduce hospital length of stay (HLOS)
3. Health economic outcomes: The cost of implementation development will be compensated for the savings in length of stay hospital resulting from decreased to incidence of Catheter-related bloodstream infections.

4. Process evaluation: The contextual and individual factors on the utilization of knowledge in clinical practice decisions and impact on hospital ward processes and practice measured by Nursing Work Index (NWI) and Evidence-Based Practice Questionnaire (EBPQ).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics and Research Committee of the Balearic Islands (CEI-IB), 20/10/2017, ref: IB 3492/17 PI

Study design
Multicentre pragmatic cluster-randomised controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Hospital

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
Adverse events/PVC failure (Catheter-related bloodstream infections, dislodgement, extravasation, obstruction and phlebitis) associated with the use of PVCs in adult hospital patients.

Interventions
20 hospital wards from five public hospitals are the clusters included in this study. All staff nurses and hospitalised adults with PVC inserted are involved in the study. Wards are randomly allocated to the intervention or control arm using software, in blocks 1:1 with stratification by setting (medical or surgical) and hospital (to ensure homogeneity of both groups). The intervention group receives the multimodal intervention implementing clinical practice guidelines whilst the control group wards continue with routine practice. Each nurse manager is provided with information to homogenise catheter removal, catheter tip culture and haemoculture extraction, to mitigate control bias. Tips from all PVC removed in patients experiencing adverse events are cultured using a semiquantitative culture. Clinical, microbiological and ward information is collected from each patient on PVC removal. The peripheral access records are adapted from our research to collect data relating to nurse practices related to use PVC.
The intervention lasts 12 months implementing evidence-based practice in healthcare related to peripheral catheters through a multimodal strategy:
1. Implementation of updated and poster protocols related to hand hygiene and aseptic measures, insertion, maintenance and removal of PVC.

2. Use of technologies applied to e-learning.
3. Feedback on the results and messages addressed to healthcare professionals to facilite adherence to recommendations
4. Facilitation of key professionals within the institution based on the PARIHS theoretical model.
5. Face-to-face training session. MasterClass related to CVP insertion, maintenance and removal will be carried out.
6. User and family information related to peripheral catheter. Informative leaflets containing recommendations adapted to the language of the patients will be provided.

Intervention Type
Mixed

Primary outcome measure
Incidence of adverse events associated with the use of PVCs is measured by assessing hospital records at 3, 6, 9, 12 months

Secondary outcome measures
1. Nurses' adherence to CPGs is measured by proportions of the following at 3, 6, 9 and 12 months:
1.1. documented nursing records of peripheral vascular accesses (complete records)
1.2. documented auditing records on peripheral vascular accesses maintenance
1.3. catheter tip extractions during removal of peripheral catheters
1.4. clinical effectiveness questionnaire in the prevention of peripheral venous catheter complications pre and post intervention.
2. Clinical outcomes are assessed using rates of catheter-related bloodstream infections, extravasation, obstruction, phlebitis, hospital mortality and mean HLOS associated with the use of PVCs at 3, 6, 9, 12 months.
3. The cost of implementing the multimodal intervention is assessed using HLOS for patients at 12 months (post intervention).

Overall study start date
01/09/2017

Completion date
01/07/2020

Eligibility

Key inclusion criteria
1. All staff nurses
2. Adult hospital patients (>18 years) with peripheral venous catheter inserted

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
20 wards and 100 participants will be included in each cluster

Total final enrolment
4478

Key exclusion criteria
1. Emergency, critical care, pediatrics, maternity, peri-operative, operative rooms, and psychiatric areas

Date of first enrolment
01/04/2018

Date of final enrolment
01/04/2019

Locations

Countries of recruitment
Spain

Study participating centre
Hospital Manacor
Manacor
Spain
07500

Study participating centre
Hospital Comarcal de Inca
Inca
Spain
07300

Study participating centre
Hospital Costa del Sol
Marbella
Spain
29603

Study participating centre
Hospital Sant Joan de Deu Palma
Palma
Spain
07007

Study participating centre
Hospital Can Misses
Eivissa
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Study participating centre
Hospital Regional Universitario de Málaga
Av. de Carlos Haya 84
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29010

Study participating centre
Hospital Universitario Márques de Valdecilla
Av. Valdecilla 25
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Sponsor information

Organisation
Evidence, Lifestyles and Health Research Group

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Sponsor type
Research organisation

Website
http://evesresearch.uib.cat/

ROR
https://ror.org/03e10x626

Funder(s)

Funder type
University/education

Funder Name
College of Nurses of the Balearic Islands

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
01/07/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Ian Blanco Mavillard (ianblanco@hmanacor.org). Individual participant data that underlie the results reported in this article, after deidentification (text, tables, figures, and appendices) will be available beginning 3 months and ending 5 years following article publication. Investigators whose proposed use of data has been approved by an independent review committee identified for this purpose for individual participant data meta-analysis. Proposals may be submitted up to 36 months following article publication.
Available documents: Study Protocol

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	25/07/2018		Yes	No
Basic results		12/08/2021	12/08/2021	No	No
Results article		01/09/2021	31/08/2021	Yes	No