

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

<b>Submission date</b> 06/03/2018	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 21/03/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 31/08/2021	<b>Condition category</b> Haematological Disorders	<input type="checkbox"/> 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)  
ianblanco@hmanacor.org

**Study website**  
<https://proyectoprebacp.wixsite.com/prebacp>

## Contact information

**Type(s)**  
Public

**Contact name**  
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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 facilitate 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  
Spain  
07800

**Study participating centre**  
**Hospital Regional Universitario de Málaga**  
Av. de Carlos Haya 84  
Málaga  
Spain  
29010

**Study participating centre**  
**Hospital Universitario Márques de Valdecilla**  
Av. Valdecilla 25  
Santander  
Spain  
39008

## **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](mailto: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?
<a href="#">Protocol article</a>	protocol	25/07/2018		Yes	No
<a href="#">Basic results</a>		12/08/2021	12/08/2021	No	No
<a href="#">Results article</a>		01/09/2021	31/08/2021	Yes	No