Devices and dressings to secure peripheral venous catheters to prevent complications (Protocol)

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Published
2014

Journal Title
Cochrane Database of Systematic Reviews

DOI
https://doi.org/10.1002/14651858.CD011070

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Devices and dressings to secure peripheral venous catheters to prevent complications (Protocol)

Marsh NM, Webster J, Rickard CM, Mihala G

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This is the protocol for a review and there is no abstract. The objectives are as follows:

To assess the effects of peripheral vascular catheter (PVC) dressings and securement devices on the incidence of PVC failure.

**ABSTRACT**

This is the protocol for a review and there is no abstract. The objectives are as follows:

To assess the effects of peripheral vascular catheter (PVC) dressings and securement devices on the incidence of PVC failure.

**BACKGROUND**

**Description of the condition**

A peripheral venous catheter (PVC), often referred to as an intravenous cannula, is a flexible, hollow, plastic tube that is inserted in a peripheral vein, most commonly the metacarpal vein of the hand, and alternatively, either the cephalic or basilic vein of the lower forearm (Tagalakis 2002; Dougherty 2008; O’Grady 2011). It is typically used for short-term delivery of intravascular fluids and medications. It is an essential element of modern medicine and the most frequent invasive procedure performed in hospital, with over 60% of all hospitalised patients requiring peripheral venous catheterisation (Wilson 2006). It has been conservatively reported that patients have a PVC for 15% to 20% of the total time they spend in an acute care hospital. (Zingg 2009). In the United States, an estimated 330 million PVC are sold each year (Hadayaw 2012).

The Infusion Nurses Society Standards recommend that PVCs be re-sited when clinically indicated, and that decisions about when to re-site should be based on an assessment of the patient’s PVC site, including: skin and vein integrity, type of intravenous (IV) therapy prescribed, the treatment setting, and patency of the PVC and securing dressing or stabilisation device (INS 2011). PVCs often fail before intravenous treatment is completed. Reported failure rates, or unscheduled restarts, range from 33% to 69% (Harwood 1992; Royer 2003; Smith 2006; Rickard 2010; Bolton 2010). PVCs fail for a wide range of reasons; the most commonly identified causes of failure are partial dislodgement or accidental removal, phlebitis (irritation or inflammation to the vein wall), occlusion/infiltration (blockage/moving into surrounding tissue) leakage and infection (Webster 2008; Bolton 2010; Rickard 2010).

**Dislodgement and accidental removal**

Inadequate catheter stabilisation or securement can lead to poor attachment of the PVC to the skin, allowing movement of the
catheter out of the vein, and resulting in partial or complete dislodgement. PVC dislodgement rates have been reported to range from 6% to as high as 20% of PVC insertions (Wood 1997; Royer 2003; Dillon 2008; Rickard 2010).

**Phlebitis**

Intravenous therapy can be disrupted by phlebitis, which is the irritation and inflammation to a vein wall caused by the presence of an intravenous device (IVD) (Monreal 1999; Tagalakis 2002). Phlebitis can be categorised as chemical (caused by infusates or medication), bacterial (caused by contamination of the site, catheter, tubing or IV solution), or mechanical (caused by the action of the catheter in the vessel) (Macklin 2003). An improperly secured IVD (intravascular device) allows micro-motion of the catheter within the vein; this can irritate the vein wall and lead to mechanical phlebitis (Sheppard 1999; Gallant 2006). Phlebitis is characterised by the presence of any combination of tenderness, pain, erythema (redness), oedema (swelling), warmth, palpable cord (hard, thickened vein), or purulent (pus) drainage (Maki 1991; Tagalakis 2002; Gallant 2006). Phlebitis rates range from 2.6% to 67.2% depending on the authors’ definition, study design, study population and the duration of follow-up period (Carney 2001; White 2001; Karadeniz 2003; Malach 2006; Webster 2008; Rickard 2010; Rickard 2012).

**Occlusion/infiltration and leakage**

A poorly-stabilised PVC within a vein can damage the vessel wall, instigating the release of thromboplastic substances and platelets that promote blood clotting (Gabriel 2010). This process may cause narrowing or occlusion of the catheterised vein, which then forces the backflow and potential leakage of IV fluids from the PVC insertion site, or their infiltration into the surrounding tissues, and restricts future venous access in the limb (Royer 2003; Gabriel 2010). Recent studies show PVC failure due to infiltration occur in 12% to 36% of patients (Homer 1998; Carney 2001; Tagalakis 2002; Webster 2008; Rickard 2010).

**Infection**

Poor catheter stabilisation, particularly if it leads to unscheduled PVC re-siting, may increase a patient’s risk of infection. In order to be sited, a PVC must be inserted through the patient’s skin, which normally acts as a protective barrier against bacteria that might otherwise access the body. Consequently the catheter may be contaminated during initial insertion or subsequent re-sittings with a new PVC (Gabriel 2008). The most common cause of catheter-related bloodstream infection (CRBSI) in short-term catheters occurs when the skin has been broken. Micro-organisms can cause local infection and may track along the surface of the PVC to contaminate the catheter tip, and then the bloodstream (Morris 2008; O’Grady 2011). Micro-motion while the PVC is in place may also encourage microbial entry via the PVC wound (Frey 2006). However, CRBSI occur less frequently in PVC than in other intravascular devices (0.1% per PVC, 0.5 per 1000 PVC-days) (Maki 2006).

Improper securement of a PVC to the skin allows the catheter to move within the vein, which increases the incidence of PVC dislodgement, mechanical phlebitis, infiltration, leakage and infection (Royer 2003; Bolton 2010; Gabriel 2010). This movement results in PVC failure, an interruption to intravenous therapy and the need to re-site the PVC. Repeated re-siting of PVC can lead to venous access difficulties, including the need for more frequent PVC re-sites or for a central venous catheter, and causing interruption to the delivery of IV therapy and a potential increase in the duration of hospital stay and healthcare costs (Monreal 1999; Tagalakis 2002; Dillon 2008).

**Description of the intervention**

The intervention of interest is the wound dressing(s) or securement device(s) used for PVC stabilisation. Following clinical practice protocols or clinician preference, two standard dressings are generally used to secure the PVC: either non-stere tape with gauze or bandage; or a transparent dressing (Gabriel 2010; O’Grady 2011). However, new products, such as antimicrobial-impregnated dressings and sutureless (stitch-less) securement devices that are designed to be used with the wound dressing to improve attachment of the PVC to the skin, have recently become available.

**Gauze/tape**

A combination of tape with bandage or gauze has been widely used to secure PVCs. This combination can range from non-sterile tape and sterile gauze assembled by clinicians using products such as Micropore® (3M) or Hypafix® (Smith & Nephew Healthcare Ltd), to commercially-available dressings that combine a sterile tape and gauze design, for example Primapore® (Smith & Nephew Healthcare Ltd). However, gauze needs to be removed so that the insertion site can be seen and this can potentially increase the chance of catheter dislodgement or movement, resulting in complications such as phlebitis, infiltration or occlusion (Campbell 1999). Furthermore, although gauze dressings are absorbent and can prevent the pooling of moisture at the insertion site, when wet they provide an ideal environment for the proliferation of infection-producing organisms (Campbell 1999; Gabriel 2010).

**Transparent dressings**

Transparent dressings have been in use since the early 1980s and offer clear visualisation of the PVC insertion site. The Opsite® (Smith & Nephew Healthcare Ltd) and Tegaderm® (3M) ranges of dressings are the most commonly used products (Webster 2011).
An early systematic review that compared gauze dressings to transparent dressings for PVC securement found a significantly higher infection risk with transparent dressings (Hoffmann 1992). This was thought to be related to increased collection of moisture (Hoffmann 1992). As a result of these studies, modern transparent dressings were developed that claim to have greater moisture vapour permeability (MVP) (Wille 1993). A study comparing standard Opsite and Opsite IV3000 for dressing central venous catheters reported MVPs of 800 g/m² and 3000 g/m², respectively and no differences between the dressings for complications such as moisture accumulation, lifting of dressing or durability (Wille 1993). Recently, new versions of these products, with additional strongly-adhesive fabric borders, or additional sterile tapes to improve securement, have become available.

**Antimicrobial dressings**

Antimicrobial dressings or impregnated discs have been developed to aid prevention of CRBSIs, for example Biopatch® (Johnson and Johnson) and Tegaderm CHG® (3M). The most common source of infection for CRBSI is colonisation of the skin surrounding the insertion site, so antimicrobial dressings aim to reduce colonisation, and thus decrease the incidence of CRBSI (Daniels 2012). The Centers for Disease Control and Prevention recommend the use of a chlorhexidine-impregnated sponge for temporary short-term catheters (typically used in intensive care units) if the central line-associated bloodstream infection (CLABSI) rates, are unacceptably high and not decreasing despite the implementation of basic preventative measures (i.e. education and training, maximal sterile barrier precautions and >0.5% chlorhexidine in an alcoholic solution for skin antisepsis) (O’Grady 2011). However, there is no mention in the Guidelines of antimicrobial sponge/dressing use in conjunction with peripheral catheters.

**Sutureless securement devices**

Sutureless securement devices have incorporated anchor points, or clips, to hold the PVC in place more securely, for example Starlock® (Bard Medical), Grip-Lok® (Zefon International) or Hubguard ® (Centurion Medical Products). It is reported that the added attachment to the skin decreases catheter movement and reduces complications such as phlebitis, dislodgement, infiltration and vessel occlusion (Schears 2006). The Centers for Disease Control and Prevention has recommended use of sutureless securement devices to decrease the risk of infection (O’Grady 2011). The Infusion Nurses Society advises that a stabilisation device should be used in preference to tape or sutures when possible, to aid in maintaining device integrity and minimisation of movement at the catheter hub (INS 2011).

**How the intervention might work**

The aim of all PVC dressings and securement devices is to maintain a barrier to infection and to ensure that the device remains in the vein. This review aims to examine the different PVC protection and stabilisation methods; the impact they have on PVC dwell time and stabilisation-related complications such as dislodgement, phlebitis, occlusion/infiltration, leaking, and infection; and the costs involved with the different products. Identification of the most effective securement method may help reduce stabilisation-related complications.

**Why it is important to do this review**

PVC insertion and IV therapy is a common procedure for hospitalised patients. Prevention of failure and unscheduled restarts of PVC therapy is an important patient outcome: failure interrupts prescribed therapy, and reinsertion can be distressing and painful. A PVC that is not securely attached to the skin has the potential to migrate externally and simply fall out, or cause complications such as phlebitis and infiltration. An inadequately secured PVC also increases the risk of CRBSI, as the pistoning action of the catheter can allow migration of organisms along the catheter and into the systemic circulation (Gabriel 2001; O’Grady 2011). These unnecessary complications can lead to delays in treatment and increases in length of hospital stay (Bolton 2010). These factors have an impact on health resources, as PVC replacement is time consuming, requires skilled clinicians and disposable sterile equipment, and CRBSIs cause significant increases in treatment costs (Bolton 2010; Gabriel 2010). Despite the many dressings and securement devices available, the impact of different securement techniques for increasing PVC dwell time is still unclear; there is a need to provide guidance for clinicians by reviewing current studies systematically.

**Objectives**

To assess the effects of peripheral vascular catheter (PVC) dressings and securement devices on the incidence of PVC failure.

**Methods**

**Criteria for considering studies for this review**

**Types of studies**

Randomised controlled trials (RCTs) comparing different dressings or securement devices for the stabilisation of PVCs. Cross-over trials will be ineligible for inclusion, unless data for the first
treatment period can be obtained. Cluster randomised controlled trials, where the cluster represents randomisation at the ward or hospital level, will be excluded.

Types of participants
Any patients in any setting who require a PVC.

Types of interventions
Any trial comparing dressings or securement devices with another dressing or securement device, for the protection or stabilisation of a PVC. Dressings or securement devices that are made from any type of product (e.g. polyurethane, gauze) will be eligible.

Types of outcome measures

Primary outcomes
- PVC failure where the PVC has been removed due to IV complications, or has fallen out.
- Adverse events related to the different types of dressings and securement devices.

Secondary outcomes
- Dislodgement and accidental removal.
- Time to catheter failure.
- Phlebitis, as identified by the trial investigator.
- Infiltration (the permeation of intravenous fluid or medication into the surrounding tissue, resulting in swelling).
- Occlusion or inability to administer intravenous fluids.
- Catheter-related blood stream infections (CRBSI) with laboratory confirmation of the catheter as the source of the infection (O'Grady 2011).
- Suspected CRBSI, as identified by the trial investigator.
- Entry site local infection, as described by the trial investigator.
- Skin damage, as described by the trial investigator.
- Cost (including cost or cost-effectiveness estimations, as well as measurements of resource use such as number of dressing/device changes, staff time).
- Patient satisfaction (using any validated instrument, e.g. a visual analogue scale).
- Pain associated with dressing removal.

Search methods for identification of studies

Electronic searches

We will search the following electronic databases to identify reports of relevant RCTs:
- The Cochrane Wounds Group Specialised Register;
- The Cochrane Central Register of Controlled Trials (CENTRAL) (latest issue);
- Ovid MEDLINE (1946 to present);
- Ovid EMBASE (1974 to present);
- EBSCO CINAHL (1982 to present).

We will use the following provisional search strategy in CENTRAL:
#1 MeSH descriptor: [Catheterization, Peripheral] explode all trees
#2 (peripheral venous catheter* or PVC):ti,ab,kw
#3 [or #1-#2]
#4 MeSH descriptor: [Occlusive Dressings] explode all trees
#5 (securement device* or Statlock or Hubguard):ti,ab,kw
#6 ((occlusive or gauze or tape or polyurethane or permeable or nonpermeable or non-permeable or transparent or antimicrobial) near/3 dressing*):ti,ab,kw
#7 (opsite or tegaderm or micropore or hypafix):ti,ab,kw
#8 [or #4-#7]
#9 [and #3, #8]

We will adopt this strategy to search Ovid MEDLINE, Ovid EMBASE and EBSCO CINAHL. We will combine the Ovid MEDLINE search with the Cochrane Highly Sensitive Search Strategy for identifying randomised trials in MEDLINE: sensitivity- and precision-maximising version (2008 revision) (Lefebvre 2011). We will combine the EMBASE search with the Ovid EMBASE filter developed by the UK Cochrane Centre (Lefebvre 2011). We will combine the CINAHL searches with the trial filters developed by the Scottish Intercollegiate Guidelines Network (SIGN 2014). We will not restrict studies with respect to language, date of publication or study setting.

We will search the following clinical trials registries:
- ClinicalTrials.gov (http://www.clinicaltrials.gov/)
- WHO International Clinical Trials Registry Platform (http://apps.who.int/trialsearch/Default.aspx)
- EU Clinical Trials Register (https://www.clinicaltrialsregister.eu/)

Searching other resources

We will search the reference lists of all relevant publications we retrieve for other studies that have not been identified by the search methods described above. We will also contact manufacturers of dressings and devices used to secure PVCs, such as Smith & Nephew Healthcare Ltd, Bard and 3M, for information about any on-going clinical trials.

Data collection and analysis
Selection of studies
Two review authors (NM and JW) will review titles and abstracts located by the search process independently. After obtaining full copies of potentially relevant studies, the same two review authors will assess their eligibility, independently, according to the inclusion and exclusion criteria. A third review author’s (CR) opinion will be sought if differences of opinion cannot be resolved by consensus.

Data extraction and management
Two review authors (NM and JW) will perform data extraction of all included RCTs independently, using a pre-designed checklist. One review author (NM) will enter data into Review Manager software (RevMan 2012), and a second review author (JW) will check the data for accuracy. If information regarding any part of the data is unclear, we will attempt to contact the study authors of the original reports and ask them to provide further details. We will include trials published as duplicate reports (parallel publications) once, using all associated trial reports to extract a maximal amount of trial information, but ensuring that the trial data are not duplicated in the review. We will extract the following information:
- participant characteristics and exclusions;
- type of dressing or securement device;
- setting;
- study dates;
- unit of investigation (participant or catheter);
- interventions;
- length of follow-up;
- information about ethics approval, consent and any declared conflicts of interest; and
- outcomes.

Assessment of risk of bias in included studies
Independently, two review authors (NM and JW) will assess the included studies for risk of bias using the ‘Risk of bias’ tool outlined in the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2011).
This assessment of bias tool addresses seven specific domains (see Appendix 1 for details), namely:
- sequence generation;
- allocation concealment;
- blinding of participants and personnel;
- blinding of outcome assessment;
- incomplete outcome data;
- selective outcome reporting;
- other possible problems that could put the study at risk of bias.
Disagreements between the two review authors (NM and JW) will be discussed and resolved by consensus, or referral to a third review author (CR). The overall assessment of the risk of bias will be presented using a ‘Risk of bias’ summary figure, which will display all judgements in a cross-tabulation of study by entry. This display of internal validity will indicate the weight the reader can give to the results of any particular study.

Measures of treatment effect
For dichotomous outcomes, we will calculate risk ratio (RR) plus 95% confidence intervals (CI). For continuous outcomes we will calculate the mean difference (MD) plus 95% CI. We will analyse any time-to-event data (e.g. time to development of phlebitis) using hazard ratios and we will not analyse time-to-event data that are incorrectly presented as continuous data.

Unit of analysis issues
Ideally a study would be designed with patient-level randomisation and analysis, and only one device per participant (adjustment for clustering not necessary in this case), however, we expect to find a number of studies that report on multiple devices per participant, randomised or analysed at device level, or both, and unadjusted for clustering.
In such cases we will contact the study authors and attempt to obtain: (1) patient-level data or results, (2) data or results for one device per participant, or (3) device-level data, and then and perform multilevel regression to calculate the adjusted effect. The adjusted results will then be combined in the meta-analysis with those of patient-level trials (using the generic inverse method), and sensitivity analyses will be performed (Higgins 2011). If we are unsuccessful in obtaining the additional data required, then the study will be excluded from the meta-analysis.
Cluster randomised controlled trials, where the cluster represents randomisation at the ward or hospital level, will be excluded.

Dealing with missing data
The missing data for each study will be identified and an attempt will be made to contact the study authors to obtain the information necessary for analysis. If the data cannot be obtained, an available-case analysis will be performed on the available data. The potential impact of missing data will be addressed in the discussion section of the review. The impact of missing data on the study results will be explored with a sensitivity analysis comparing the results from the analyses of study completers with those from best-case and worst-case scenarios. In the best-case scenario, all missing data from the treatment group will be considered not to indicate PVC failure, while those missing from the control group will be considered to indicate PVC failure. In the worst-case scenario missing data from the treatment group will be considered to indicate PVC failure, while those missing from the control group will be considered not to indicate PVC failure.
**Assessment of heterogeneity**

Statistical heterogeneity will be tested for by using the Chi^2 test, with significance set at a P value of less than 0.10. In addition, the degree of heterogeneity will be investigated by calculating the I^2 statistic (Deeks 2011). This describes the percentage of the variability in effect estimates that is due to heterogeneity rather than sampling error (chance). A rough guide to interpretation is as follows: 0 to 40%: might not be important; 30% to 60%: may represent moderate heterogeneity; 75% to 100%: represents considerable heterogeneity (Deeks 2011). The importance of the observed value of I^2 depends on (1) the magnitude and direction of effects, and (2) the strength of evidence for heterogeneity (e.g. P value from the Chi^2 test, or a confidence interval for I^2) (Deeks 2011).

**Assessment of reporting biases**

If there are 10 or more studies included in our meta-analysis, we will assess for reporting bias by using a funnel plot. If visual inspection of the symmetry of the funnel plot shows that reporting bias is present, we will include a statement in our results and a note of caution in our discussion. Where possible, we will also access trial protocols and compare the outcome measurements planned with those reported.

**Data synthesis**

Review Manager will be used to perform the meta-analysis of included studies (RevMan 2012). For dichotomous outcomes, we will calculate risk ratio (RR) plus 95% confidence intervals (CI). For continuous outcomes we will calculate the mean difference (MD) plus 95% CI. If evidence of significant heterogeneity is identified (i.e. greater than 50%), potential causes will be explored, and we will use a random-effects approach to the analysis, otherwise we will use a fixed-effect method.

**Subgroup analysis and investigation of heterogeneity**

- Children (under 16 years of age) and adults.
- Continuous versus intermittent IV therapy.
- Additional bandaging versus dressing or securement device alone.

**Sensitivity analysis**

We will perform sensitivity analysis to assess for the following:

- adequate concealment of allocation;
- size of studies (less than 100 patients);
- follow-up period of up to 48 hours;
- missing data - best/worst case scenarios.

**'Summary of findings' table**

We will present the main results of the review in 'Summary of findings' tables. These tables present key information concerning the quality of the evidence, the magnitude of the effects of the interventions examined, and the sum of the available data for the main outcomes (Schünemann 2011a). The 'Summary of findings' tables also include an overall grading of the evidence related to each of the main outcomes using the GRADE (Grading of Recommendations Assessment, Development and Evaluation) approach (Schünemann 2011b). The GRADE approach defines the quality of a body of evidence with regard to the extent to which one can be confident that an estimate of effect or association is close to the quantity of specific interest. Quality of a body of evidence involves consideration of within-trial risk of bias (methodological quality), directness of evidence, heterogeneity, precision of effect estimates and risk of publication bias (Schünemann 2011b). We plan to present the following outcomes in the 'Summary of findings' tables:

- proportion of failed catheters;
- time to catheter failure;
- adverse events.

**Acknowledgements**

The authors would like to acknowledge the contribution of the peer referees: Anneke Andriessen, Kurinchi Gurusamy, Richard Kirubakaran, Ros Wade and Janet Wale, and copy editor Elizabeth Royle.
Additional references

Bolton 2010

Campbell 1999

Catney 2001

Dainiels 2012

Deeks 2011

Dillon 2008

Dougherty 2008

Frey 2006

Gabriel 2001

Gabriel 2008

Gabriel 2010

Gallant 2006

Haddaway 2012

Harwood 1992

Higgins 2011

Hoffmann 1992

Homer 1998

INS 2011

Karadeniz 2003

Lefebvre 2011

Macklin 2003

Maki 1991

Maki 2006
Maki DG, Kluger DM, Crnich CJ. The risk of bloodstream infection in adults with different intravascular devices: a

**Malach 2006**


**Monreal 1999**


**Morris 2008**


**O’Grady 2011**


**RevMan 2012**


**Rickard 2010**


**Rickard 2012**


**Royer 2003**


**Schears 2006**


**Schünemann 2011a**


**Schünemann 2011b**


**Sheppard 1999**


**SIGN 2014**


**Smith 2006**


**Tagalakis 2002**


**Webster 2008**


**Webster 2011**


**White 2001**


**Wille 1993**


**Wilson 2006**


**Wood 1997**

A P P E N D I C E S

Appendix 1. ‘Risk of bias’ table judgement criteria

1. Was the allocation sequence generated adequately?
   - **Low risk of bias** - adequate sequence generation is described in sufficient detail for example, using a computer random number generator, random number tables, coin tossing or shuffling envelopes
   - **High risk of bias** - non-random component in sequence generation is described by the author. This description usually involves a systematic non-random approach, for example, sequence generated by odd or even date of birth; by a rule based on date of admission or on hospital or clinic record number.
   - **Unclear** - Insufficient information about the sequence generation provided to make a judgement of risk of bias.

2. Was the allocation sequence adequately concealed?
   - **Low risk of bias** - participants and investigators enrolling participants could not foresee allocation assignment because one of the following methods was used for allocation concealment: central allocation, for example, via telephone, web-based and pharmacy-controlled randomisation; sequentially-numbered drug containers of identical appearance; sequentially-numbered opaque, sealed envelopes.
   - **High risk of bias** - participants or investigators enrolling participants could possibly foresee assignments and thus introduce selection bias, such as allocation based on: an open random allocation schedule; assignment without appropriate safeguards, for example non-opaque envelopes or envelopes that were not sequentially-numbered; alternation of rotation; date of birth; case record number; or any other unconcealed procedure.
   - **Unclear** - Insufficient information about the concealment provided to make a judgement of risk of bias.

3. Blinding of participants and personnel - was knowledge about the allocation of interventions adequately prevented during the study?
   - **Low risk of bias** - either of the following: no blinding or incomplete blinding, but the review authors judge that the outcome is not likely to be influenced by the lack of blinding; blinding of participants and the study personnel ensured, and unlikely that the blinding could have been broken.
   - **High risk of bias** - either of the following: no blinding or incomplete blinding, and the outcome is likely to be influenced by lack of blinding; blinding of key study participants and personnel attempted, but likely that the blinding could have been broken and the outcome is likely to be influenced by lack of blinding.
   - **Unclear** - either of the following: insufficient information provided to permit judgement of risk of bias; or the study did not address the outcome.

4. Blinding of outcome assessment - was knowledge of the allocated interventions adequately prevented during the study?
• **Low risk of bias** - either of the following: no blinding of outcome assessment but the review authors judge that the outcome measurement is not likely to be influenced by the lack of blinding; blinding of the outcome assessment ensured, and unlikely that the blinding could have been broken.

• **High risk of bias** - either of the following: no blinding of outcome assessment and the outcome measurement is likely to be influenced by lack of blinding; blinding of outcome assessment, but likely that the blinding could have been broken, and the outcome measurement is likely to be influenced by the lack of blinding.

• **Unclear** - either of the following: insufficient information provided to permit judgement of risk of bias; or the study did not address this outcome.

5. **Were incomplete outcome data adequately addressed?**

• **Low risk of bias** - any one of the following: no missing outcome data; reasons for missing outcome data are unlikely to be related to true outcome (for survival data, censoring is unlikely to be introducing bias); missing outcome data balanced in numbers across intervention groups, with similar reasons for missing data across groups; for dichotomous outcome data, the proportion of missing outcomes compared with observed event risk is not enough to have a clinically relevant impact on the intervention effect estimate; for continuous outcome data, plausible effect size (difference in means or standardised difference in means) among missing outcomes is not enough to have a clinically relevant impact on observed effect size; missing data have been imputed using appropriate methods.

• **High risk of bias** - any one of the following: reason for missing outcome data is likely to be related to true outcome, with either imbalance in numbers or reasons for missing data across intervention groups; for dichotomous outcome data, the proportion of missing outcomes compared with observed event risk is enough to induce clinically relevant bias in intervention effect estimate; for continuous outcome data, plausible effect size (difference in means or standardised difference in means) among missing outcomes is enough to induce clinically relevant bias in observed effect size; ‘as-treated’ analysis done with substantial departure of the intervention received from that assigned at randomisation; potentially inappropriate application of simple imputation.

• **Unclear** - either of the following: insufficient reporting of attrition/exclusions to permit judgement of low or high risk of bias (e.g. number randomised not stated, no reasons for missing data provided); the study did not address this outcome.

6. **Are reports of the study free of suggestion of selective outcome reporting?**

• **Low risk of bias** - either of the following: the study protocol is available and all of the study’s pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way; the study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were pre-specified (convincing text of this nature may be uncommon).

• **High risk of bias** - any one of the following: not all of the study’s pre-specified primary outcomes have been reported; one or more primary outcomes is reported using measurements, analysis methods or subsets of the data (e.g. subscales) that were not pre-specified; one or more reported primary outcomes were not pre-specified (unless clear justification for their reporting is provided, such as an unexpected adverse effect); one or more outcomes of interest in the review are reported incompletely so that they cannot be entered in a meta-analysis; the study report fails to include results for a key outcome that would be expected to have been reported for such a study.

• **Unclear** - insufficient information provided to permit judgement of risk bias.

7. **Other sources of potential bias**

• **Low risk of bias** - the study appears to be free of other sources of bias.

• **High risk of bias** - there is at least one important risk of bias, for example the study: had a potential source of bias related to the specific study design used; or had extreme baseline imbalance; or has been claimed to have been fraudulent; or had some other problem.

• **Unclear** - there may be a risk of bias, but there is either: insufficient information to assess whether an important risk of bias exists; or insufficient rationale or evidence that an identified problem will introduce bias.
Appendix 2. Glossary

Colonisation: the presence of bacteria or other micro-organisms in a specific body part or a device in the body.

Dwell time: number of hours/days that a device remains in a patient.

Erythema: redness or inflammation of the skin.

Intravascular device: a catheter or device that is placed within a vessel (vein or artery) and used for intravascular access

Intravascular fluids: liquid that is delivered intravascularly, usually from a fluid bag, via a line or administration set and through an intravascular device.

Peripheral venous catheter (PVC): a flexible, hollow, plastic tube that is inserted into a peripheral vein

Phlebitis: irritation to a vein wall caused by the presence of an intravascular device

Skin integrity: a description of a patient’s skin, whether it is intact or not

Contributions of Authors

Nicole Marsh: conceived and developed the protocol and co-ordinated its development, completed the first draft of the protocol, made an intellectual contribution, approved the final version prior to submission.

Joan Webster: conceived and developed the protocol and co-ordinated its development, completed the first draft of the protocol, made an intellectual contribution, approved the final version prior to submission.

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Nicky Callum: edited the protocol; advised on methodology, interpretation and protocol content.

Liz McInnes, Editor: approved the final protocol prior to submission.

Sally Bell-Syer: coordinated the editorial process. Advised on methodology, interpretation and content. Edited the protocol.

Ruth Foxlee: designed the search strategy and edited the search methods section.

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Declarations of Interest

Nicole Marsh and Claire Rickard received a grant-in-aid from BD Medical Australia Ltd to fund an unrelated research study. BD Medical Australia Ltd will have no involvement in the analysis of data or preparation of the manuscript for publication. The same manufacturer also co-funds (with the university) an unrestricted PhD scholarship for one of Claire Rickard's students.

Gabor Mihala and Joan Webster: nothing to declare

Sources of Support

Devices and dressings to secure peripheral venous catheters to prevent complications (Protocol)
**Internal sources**

- No sources of support supplied

**External sources**

- The National Institute for Health Research (NIHR) is the sole funder of the Cochrane Wounds Group, UK.