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Efficacy and safety of a two-step method of skin preparation for peripheral intravenous catheter insertion - a prospective multicentre randomised trial

Submission date
22/05/2006

Recruitment status
No longer recruiting

Registration date
19/06/2006

Overall study status
Completed

Last Edited
02/09/2021

Condition category
Circulatory System

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Study information

Scientific Title

Efficacy and safety of a two-step method of skin preparation for peripheral intravenous catheter insertion - a prospective multicentre randomised trial

Study objectives
Thrombophlebitis is an early sign, preceding infection, frequently associated with infectious complications of the use of Peripheral Venous Catheters (PVCs). It occurs more than 24 hours after insertion, in 12 to 34% of cases and more than 48 hours after insertion, in 36 to 65% of cases. The observation of local complications associated with PVCs, and the comparison of their frequency as a function of certain criteria (nature of the catheter, antiseptic used, insertion site etc.) have previously been used to study the risk factors for PVC-linked infections. In 1983, Maddox et al. conducted a prospective double-blind study with 195 men to evaluate the effect of inline intravenous filters on post infusion phlebitis and bacterial colonization of catheters. Gabel et al. conducted a comparative study of a new skin preparation method for peripheral intravenous lines and studied in 60 patients the incidence of PVC infection in relation to skin preparation methods. The insertion sites were then evaluated for multiple signs including redness, inflammation, pain or tenderness. In 1989, Jacquot et al. conducted a study which compared peripheral intravenous Teflon® and Vialon® catheters. The incidence of phlebitis was then assessed on 170 PVCs.

Strict compliance with skin preparation procedures before insertion of the catheter is one of the principal means of preventing PVC-linked infection. Nevertheless, the procedures for the insertion and care of a PVC are poorly adhered to in routine practice. This lack of compliance may be attributed to the time-consuming nature of the recommended procedure. With the intention of encouraging compliance with the recommendations, we have developed a simplified, effective method for skin preparation for the insertion of PVCs, involving two successive swabbings with alcoholic antiseptic imbibed compresses.

Based on these data, we therefore carried out a randomised equivalence study comparing the frequency of signs of thrombophlebitis at the site of insertion for the two procedures, the two-step procedure and the standard four-step procedure.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval not required according to the Ethical Committee of the Medical Regional Center, dated 17/12/2003

Study design
A prospective, multicentre, randomised equivalence study

Primary study design
Interventional

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Catheter-related septic thrombophlebitis

Interventions
With the intention of encouraging compliance with the recommendations, we have developed a simplified, effective method for skin preparation for the insertion of PVCs, involving two successive swabbings with alcoholic antiseptic imbibed compresses.

There will be two procedures tested in this trial:
1. The two-step procedure
2. The standard four-step procedure

PVCs were inserted and maintained by nursing staff. The investigators were responsible for checking that the prescribed skin preparation protocol was adhered to and for collecting data concerning possible confounding factors. These included the age of the patient, immunosuppression, nature of the catheter, number of manipulations per day, duration of catheterisation and the nature of the perfused solutes.

Inspection of the insertion site is a key part of nursing care. The patients were monitored daily throughout the time of perfusion, until withdrawal of the catheter, for a maximum of 72 hours.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
The appearance of precursor signs of infection at the insertion site, as evaluated according to the Maddox scale. The nurses were trained in the use of this scale before the start of the study.

Key secondary outcome(s))
No secondary outcome measures

Completion date
01/12/2004

Eligibility

Key inclusion criteria
1. Hospitalised, consenting adults aged over 18 years
2. Male or female
3. Requiring the insertion of a continuous PVC with a treatment duration of more than 48 hours
4. Those for whom either skin preparation procedure could be used

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
248

Key exclusion criteria
1. The insertion of a catheter for emergency perfusion
2. Allergy to povidone
3. A planned intravenous treatment time of less than 48 hours
4. The presence of skin lesions at the chosen insertion site
5. Being in the last three months of pregnancy
6. Refusal to give consent
7. Patient unconscious or incapable of understanding the information given

Date of first enrolment
01/05/2004

Date of final enrolment
01/12/2004

Locations

Countries of recruitment
France

Study participating centre
CHU Tours
Tours
France
37044

Sponsor information

Organisation
West Scientific Coordination Center for the Fight against Nosocomial Infections (CCLIN) (France)

Funder(s)

Funder type

Hospital/treatment centre

Funder Name
West Scientific Coordination Center for the Fight against Nosocomial Infections (Centre de Coordination de Lutte Contre les Infections Nosocomiales Ouest [CCLIN]) (France)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		31/01/2007	02/09/2021	Yes	No