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A clinical evaluation of a CVC securement device

Submission date
08/07/2015

Recruitment status
No longer recruiting

Registration date
09/07/2015

Overall study status
Completed

Last Edited
23/04/2019

Condition category
Signs and Symptoms

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

Plain English summary of protocol

Background and study aims
Central venous catheters (CVC) are inserted into many patients for the administration of treatment and haemodynamic monitoring (for measuring blood pressure and oxygen levels in the blood) . Sutures (stitches) are frequently used to secure CVC onto the skin, however application of sutures carries a risk of needle stick injury to the clinician, discomfort to the patient and trauma at the CVC insertion site. Moreover, the sutures securing CVC are often highly colonized with bacteria despite scrupulous CVC site care, and may serve as a source for an infection. CVC movement may introduce microorganisms from the skin surface along the CVC and contribute to an infection. Therefore alternative securement methods for short term CVC needs to be tested. Alternative CVC securement methods are available, such as adhesive devices /tapes/dressings; however these have been used for securing CVC that are placed through veins in the arm. Knowledge of securement device for CVC, which are inserted into neck, chest or groin, is limited. This study will test the safety of the device, whether what is being measured is appropriate and measurable and whether the device is acceptable to clinical users.

Who can participate?
Adults (18 or over) being treated, or about to be treated, in a critical care unit and needing a CVC.

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 have sutures securing their CVC. Those in group 2 have the CVC securement device applied to secure the CVC. The patients are observed for any CVC related complications and CVC placement is measured daily. Comfort of the patient and user acceptability is evaluated where appropriate.

What are the possible benefits and risks of participating?
Participants may not have any direct medical benefit from being in this study; however the information gained from this study will help improve the treatment of future patients who have a catheter inserted as part of their medical care. Catheter stabilization is recognised as an intervention to decrease the risk for phlebitis and catheter displacement, and may be advantageous in preventing catheter related bloodstream infections. Risks include skin irritation and damage to the skin, improper use of the catheter securement system or displacement of it, infection and air embolism.

Where is the study run from?
University Hospitals Birmingham NHS Foundation Trust (UK).

When is the study starting and how long is it expected to run for?
June 2014 to June 2017

Who is funding the study?
3M Deutschland GmbH

Who is the main contact?
Dr Tarja Karpanen

Contact information

Type(s)
Scientific

Contact name
Dr Tarja Karpanen

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
18974

Study information

Scientific Title
A clinical evaluation of two central venous catheter stabilization systems

Study objectives
The aim of this feasibility study is to assess the safety of a new securement device for central venous catheters (CVC), to see whether the proposed study parameters are appropriate and measurable, and the securement device is acceptable to clinical users.

Ethics approval required

Old ethics approval format

Ethics approval(s)
NRES Committee North West – Greater Manchester South, 27/04/2015, ref: 15/NW/0185

Study design
Randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Topic: Critical care; Subtopic: Critical care; Disease: All Critical care

Interventions
CVC securement: a short-term central venous catheter is secured onto the skin using either sutures and a transparent dressing, or a sutureless securement system which consists of a molded plastic device with an adhesive backing and a transparent film dressing.

Intervention Type
Device

Primary outcome measure
Total number of catheter dislodgements. Recorded daily (for the duration of CVC placement) using standard clinical observation methods.

Secondary outcome measures
1. Number of complete catheter dislodgements (i.e. number of unplanned catheter removals)
2. Number of partial catheter dislodgement: (i.e. catheter migration at the skin insertion site but not resulting in unplanned catheter removal; measured in mm)
3. Securement device adherence onto skin and catheter (full or partial)
4. Number of catheters requiring immediate repositioning of securement device
5. Number of dressing changes per catheter
6. Number of reported unresolved occlusions of the catheter
7. Catheter insertion site visible on routine clinical inspection (yes or no)
8. Number of patients requiring an alternative catheter securement method to which the subject was originally selected
9. Reasons for requiring an alternative catheter securement method to which the subject was

originally selected
10. Clinical staff satisfaction (questionnaire)
11. Patient comfort level: subjective (pain score if able to communicate) and objective evaluation (skin condition) on application and removal of the securement device

Recorded daily (for the duration of CVC placement) using standard clinical observation methods

Overall study start date
18/06/2014

Completion date
14/06/2017

Eligibility

Key inclusion criteria
1. ≥18 years of age
2. Admitted, or to be admitted, to a critical care unit
3. Require a single, short-term, non-cuffed, non-tunnelled CVC (up to and including 12F in size) as part of their clinical care
4. Willing and able to provide written informed consent (or if their condition do not allow this their legally authorized representative willing and able to give the consent on their behalf)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 168; UK Sample Size: 42

Total final enrolment
186

Key exclusion criteria
1. Confused (patients who have a positive CAMICU score or if confusion expected after sedation stopped)
2. Excessively perspiring (skin becomes moist within 2 minutes of drying)
3. Non adherent skin burn, trauma or other condition affecting the skin integrity in close proximity to the potential insertion site, so that the device/ suture is applied to the skin without any of these conditions
4. Underlying uncorrected bleeding diathesis
5. Known allergy to adhesives or device components

6. To have more than one catheter inserted at the same location
7. Pregnant or breastfeeding women
8. Past participants in this study

Date of first enrolment
08/09/2015

Date of final enrolment
31/01/2017

Locations

Countries of recruitment
England

France

Spain

United Kingdom

Study participating centre
University Hospitals Birmingham NHS Foundation Trust
Birmingham
United Kingdom
B15 2GW

Study participating centre
Bichat-Claude Bernard Hopital
Paris
France
75018

Study participating centre
University Hospital (Centre Hospitalier Universitaire), Universite de Poitiers et Inserm
Poitiers
France
86021

Study participating centre

University Hospital Arnau de Vilanova (University Hospital Arnau de Vilanova)
Lleida
Spain
25198

Sponsor information

Organisation
University Hospitals Birmingham NHS Foundation Trust

Sponsor details
Research and Development Department
Heritage Building (Queen Elizabeth Hospital)
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/014ja3n03

Funder(s)

Funder type
Industry

Funder Name
3M Deutschland GmbH

Results and Publications

Publication and dissemination plan
This is a feasibility study. The results may be published in a scientific journal or presented at a scientific meeting.

Intention to publish date
14/06/2018

Individual participant data (IPD) sharing plan

The datasets are not made publicly available as consent from patients were not sought for data to be used for other research/sent outside of EU

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		06/09/2018	06/09/2018	No	No
Results article	results	17/04/2019	23/04/2019	Yes	No
HRA research summary			28/06/2023	No	No