

Ultrasound versus chest radiography after central venous catheter insertion

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| Submission date 20/05/2012 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 07/06/2012 | Overall study status Stopped | <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results |
| Last Edited 15/05/2018 | Condition category Surgery | <input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year |

Plain English summary of protocol

Background and study aim

A central venous catheter (CVC) is a device inserted into a large vein for drug and fluid administration, cardiovascular (heart) monitoring and kidney support. It is commonly used in critically ill patients or those having major surgery. A CVC can be inserted in the neck (internal jugular), close to the chest (subclavian) or in groin veins (femoral). When inserted in the internal jugular or subclavian veins, a chest x-ray is usually performed afterwards to confirm the catheter is in the correct position and check for injury to the lung (pneumothorax). In the past CVC placement was done as a blind procedure based on anatomical landmarks. In 2002 the National Institute for Health and Clinical Excellence (NICE) recommended the use of ultrasound to guide CVC insertion. The use of ultrasound has improved the success rate and reduced the complications previously associated with CVC insertion. This study addresses the question of whether ultrasound can serve as a diagnostic tool following CVC insertion instead of a chest x-ray.

Who can participate?

Adult patients in whom the attending Intensivist or Anaesthetist decides to insert a CVC and for which a chest x-ray would normally be performed.

What does the study involve?

The decision to insert a CVC is based on the clinical judgement of the attending Intensivist or Anaesthetist. After CVC insertion a member of the research team is contacted to perform the ultrasound examination. The standard series of ultrasound images is checked to confirm the correct CVC position, and identify catheter misplacement or punctured lung (pneumothorax). The ability to record these standard ultrasound images, the quality of the images and the image findings are recorded by the researcher. All patients subsequently have a chest x-ray as is the normal practice after CVC insertion. The accuracy of information provided by the ultrasound is compared to that from the chest x-ray.

What are the possible benefits and risks of participating?

All patients will have a chest x-ray, which is the normal check, in addition to an ultrasound examination. This should increase the chance of diagnosing any complications. The ultrasound examination is non-invasive and does not cause pain or discomfort.

Where is the study run from?
The Royal Sussex County Hospital (UK)

When is the study starting and how long is it expected to run for?
June 2012 to May 2013

Who is funding the study?
The Royal Sussex County Hospital (UK)

Who is the main contact?
Dr J.A. Ezihe-Ejiofor
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CVC-01

Study information

Scientific Title
Can ultrasound examination safely replace chest radiography after central venous catheter insertion? A feasibility study

Study objectives
An ultrasound examination can produce images of sufficient diagnostic quality to enable it serve as a post procedure check instead of chest x-ray after central venous catheter insertion. This will

obviate the need for routine chest x-ray, avoid unnecessary patient exposure to radiation and minimize delays in starting therapy while waiting for radiography.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Prospective cross-over trial

Primary study design

Interventional

Secondary study design

Randomised cross over trial

Study setting(s)

Hospital

Study type(s)

Diagnostic

Participant information sheet

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

Health condition(s) or problem(s) studied

Central venous catheter insertion and ultrasound examination

Interventions

All patients will have an ultrasound examination of the heart and chest post CVC insertion.

Intervention Type

Procedure/Surgery

Phase

Not Applicable

Primary outcome measure

1. Successful use of the ultrasound examination to generate images of sufficient diagnostic quality to facilitate a post CVC insertion check.
2. Successful use of the images generated in (a) to enable the operator:
 - 2.1. Identify correct CVC tip position
 - 2.2. Exclude CVC misplacement
 - 2.3. Exclude a pneumothorax

Secondary outcome measures

1. The time taken to complete the ultrasound examination
2. The time taken from contacting the radiology department to the chest radiograph becoming available to view on the Picture Archiving and Communication System (PACS)

Overall study start date

01/06/2012

Completion date

01/05/2013

Reason abandoned (if study stopped)

Lack of staff/facilities/resources

Eligibility

Key inclusion criteria

Adult patients in whom the attending clinician plans to insert a central venous catheter (CVC) into the internal jugular or subclavian vein and for which a routine post procedural chest x-ray would normally be done.

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

200

Key exclusion criteria

1. Patients less than 16 years old
2. Adult patients in whom the attending clinician plans to insert a central venous catheter (CVC) into the groin (femoral) vein as a chest x-ray is not normally done for this insertion route
3. Patients who refuse to give consent for the ultrasound examination

Date of first enrolment

01/06/2012

Date of final enrolment

01/05/2013

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

The Royal Sussex County Hospital
Brighton
United Kingdom
BN2 5BE

Sponsor information

Organisation

Brighton and Sussex University Hospitals NHS Trust (UK)

Sponsor details

The Royal Sussex County Hospital
Eastern Road
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United Kingdom
BN2 5BE
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Scott.Harfield@bsuh.nhs.uk

Sponsor type

Hospital/treatment centre

Website

<http://www.bsuh.nhs.uk/>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Royal Sussex County Hospital (UK)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration