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# Placing newborn infants on their Back Or Right side for Umbilical venous catheter (UVC) insertion

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 03/09/2013 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 14/10/2013 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 21/01/2019 | Neonatal Diseases | |

## Plain English summary of protocol

Background and study aims
Some newborn babies have lines inserted into a large blood vessel in their umbilical cord (umbilical venous catheter - UVC) so they can receive fluid, blood products and drugs. It is important that the tip of the UVC is in the midline near the heart so that these products are delivered into a large volume of circulating blood. Babies are placed on their back when UVCs are inserted. The position of the UVC tip is confirmed with an X-ray. Up to half of UVCs inserted into infants lying on the back end up in a smaller blood vessel on the right side near the liver. We aim to find out whether placing babies on the right side results in more UVCs in the correct position on X-rays.

Who can participate?
Newborn infants who are having a UVC inserted can participate in the study.

What does the study involve?
Infants re randomly allocated to one of two groups: being placed on their back or on their right side during UVC insertion. The position of the insertion is analysed using an X-ray.

What are the possible benefits and risks of participating?
Participants will not have extra investigations or treatments due to their participation in the study. There are no risks to participants above those incurred by any infant who has a UVC inserted.

Where is the study run from?
The National Maternity Hospital, Dublin, Ireland.

When is study starting and how long is it expected to run for?
The study started in September 2013 and is expected to run for 12 months.

Who is funding the study?
National Childrens Research Centre, Dublin, Ireland.

Who is the main contact?
Dr Colm ODonnell
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# Contact information

### Type(s)
Scientific

### Contact name
Dr Colm O'Donnell

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Neonatal Intensive Care Unit
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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
BORU001

# Study information

### Scientific Title
A randomised trial of placing newborn infants on their back or right side during umbilical venous catheter insertion

### Acronym
BORU

### Study objectives
Placing newborn infants who are having umbilical venous catheters inserted on their right side, compared to the back, results in an increased rate of correctly sited umbilical venous catheters.

On 04/06/2014 the anticipated end date was changed from 30/06/2014 to 30/05/2014.

### Ethics approval required

Old ethics approval format

## Ethics approval(s)
Ethics Committee at the National Maternity Hospital, Dublin, Ireland; 25/06/2013

## Study design
Randomised controlled trial

## 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 the contact details below to request a patient information sheet

## Health condition(s) or problem(s) studied
Critical care of the newborn infant

## Interventions
Infants will be randomly allocated to the 'right side' or 'back' groups.
1. Infants randomised to back positioning will remain on their back and have the UVC inserted.
2. Infants who are randomised to right side shall be turned 90 degrees onto the right side and then have the UVC inserted.
Once the UVC is in place all infants shall be placed back on their back. UVCs will be sutured in place and the position will be determined with a chest and abdominal X-ray.

## Intervention Type
Other

## Phase
Not Applicable

## Primary outcome measure
Correct placement of the UVC defined as the catheter-tip being in the midline at diaphragm level on the X-ray taken to confirm catheter position. The position of the catheter tip will be determined by a consultant radiologist who is masked to the infants group assignment.

## Secondary outcome measures
1. The successful insertion of the UVC
2. Corresponding vertebral level of UVC tip on X-ray
3. Number of UVC insertion attempts and successful
4. Replacement or repositioning of UVC post confirmation X-ray

5. Total number of x-rays performed to confirm line position
6. Pericardial effusions
7. Pleural effusions
8. Air leaks
9. Cardiac arrhythmias
10. Gastrointestinal perforation
11. Necrotising enterocolitis
12. Time to 120 ml/kg/day enteral feeds
13. Cranial ultrasound abnormalities (intraventricular hemorrhage and periventricular leukomalacia)
14. Total duration of umbilical catheters in situ (days)
15. Catheter related blood stream infection
16. Duration of hospital stay (days)
17. Death before discharge

### Overall study start date
16/09/2013

### Completion date
30/05/2014

## Eligibility

### Key inclusion criteria
1. Infants will be eligible for enrollment in this study if they are having a UVC inserted in the Neonatal Intensive Care Unit (NICU)
2. Infants born outside the National Maternity Hospital will be eligible for enrollment if they have not undergone umbilical catheterization in the referring hospital

### Participant type(s)
Patient

### Age group
Neonate

### Sex
Both

### Target number of participants
88

### Key exclusion criteria
1. Infants who have previously had a UVC inserted at a referring hospital
2. Infants with major congenital anomalies that may alter internal anatomy (e.g. gastroschisis, exomphalos or congenital diaphragmatic hernia)

### Date of first enrolment
16/09/2013

### Date of final enrolment

30/05/2014

# Locations

### Countries of recruitment
Ireland

### Study participating centre
**Neonatal Intensive Care Unit**
Dublin
Ireland
2

# Sponsor information

### Organisation
The National Maternity Hospital (Ireland)

### Sponsor details
c/o Colm O'Donnell
Neonatal Intensive Care Unit
Holles Street
Dublin
Ireland
2

### Sponsor type
Hospital/treatment centre

### ROR
https://ror.org/03jcxa214

# Funder(s)

### Funder type
Research organisation

### Funder Name
National Children's Research Centre, Dublin, Ireland

# 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

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 01/10/2016 | 21/01/2019 | Yes | No |