

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

Submission date 03/09/2013	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 14/10/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 21/01/2019	Condition category Neonatal Diseases	<input type="checkbox"/> Individual participant data

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 are 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 O'Donnell
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Contact information

Type(s)

Scientific

Contact name

Dr Colm O'Donnell

Contact details

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Neonate

Sex

All

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

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Sponsor information

Organisation

The National Maternity Hospital (Ireland)

ROR

<https://ror.org/03jcxa214>

Funder(s)

Funder type

Research organisation

Funder Name

National Children's Research Centre, Dublin, Ireland

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	results	01/10/2016	21/01/2019	Yes	No