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

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>			
03/09/2013		Protocol			
Registration date 14/10/2013	Overall study status Completed	Statistical analysis plan			
		[X] Results			
<b>Last Edited</b> 21/01/2019	Condition category Neonatal Diseases	[] 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 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 codonnell@nmh.ie

# 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

# **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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes