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Using birth weight or surface measurements for estimating insertion depth of umbilical catheters in newborn infants

Submission date
07/07/2012

Recruitment status
No longer recruiting

Registration date
22/08/2012

Overall study status
Completed

Last Edited
13/08/2015

Condition category
Neonatal Diseases

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

Plain English summary of protocol

Background and study aims
Many newborn babies need to be admitted to the neonatal intensive care unit (NICU) after birth. Some of these babies have catheters (small plastic tubes) put into the blood vessels (arteries and veins) of the cut end of the umbilical cord. Through the venous catheters babies can be given drugs and fluids, and their blood pressure can be monitored. Blood samples can be taken from the arterial catheters. It is important that the ends of the catheters are in good positions so that they work well and so that the risks of side effects are reduced. Doctors estimate how far they should insert these catheters using one of two methods. One method uses the birth weight of the baby and the other formula uses a measurement of the distance between the baby's shoulder and umbilicus (belly button). Currently we do not know which method is more accurate at estimating how far to insert the catheters. It is important to know this so that we can reduce the complications that can occur when catheters are inserted in the incorrect position. The aim of our study is to find out which method is more accurate in predicting how far to insert the catheters.

Who can participate?
Any infants who are admitted to the NICU after they are born and need to have a catheter inserted into their umbilical vein and/or artery can be included in the study.

What does the study involve?
If a baby in included in the study he or she will be randomly allocated to have the catheters inserted using one of the two methods. The research team will then collect data from the baby's chart to find out how he or she gets on until discharge from hospital. The baby will not have extra investigations or treatments compared with infants who do not participate in the study.

What are the possible benefits and risks of participating?
Umbilical catheter insertion is a commonly performed procedure in the intensive care unit. We only decide to put in these catheters in a baby if we feel it is in their best interest. It is possible that one treatment allocated to a baby may be more effective than the other treatment but this will not be known until the end of the study when the data from all the babies has been

analysed. The results of this study will be important in helping improve the care of babies in the future. There will be no more risks for a baby in this study than for any other ill baby needing umbilical catheter insertion and intensive care treatment. Babies who participate in this study will not experience discomfort, side effects or inconvenience other than that encountered in the normal course of their treatment.

Where is the study run from?
The study is being carried out in the neonatal intensive care unit at The National Maternity Hospital, Dublin, Ireland.

When is the study starting and how long is it expected to run for?
The study is starting in July 2012 and it is expected to run for 18 months.

Who is funding the study?
The study is being funded by the National Children's Research Centre, Dublin, Ireland.

Who is the main contact?
Dr Colm O'Donnell
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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
WORM001

Study information

Scientific Title
A randomised trial of using birth weight or surface measurements for estimating insertion depth of umbilical catheters in newborn infants

Acronym
WorM

Study objectives
Estimating depth of insertion of umbilical catheters in newborn infants using a birth weight derived formula is more accurate than estimating insertion depth using graphs derived from anatomical measurements.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The National Maternity Hospital Ethics Committee, Dublin, Ireland, 05/01/2012

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

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 'WEIGHT' or 'MEASUREMENT' calculation groups.

Infants randomised to 'WEIGHT' will have the depth of insertion calculated as follows:
UVC - depth of insertion (cm) = [1.5 x birth weight (kg)] + 5
UAC - depth of insertion (cm) = [3 x birth weight (kg)] + 9

Infants randomised to 'MEASUREMENT' will have the distance from their shoulder tip to umbilicus measured; and this measurement will be used to determine the insertion depth from a graph designed and widely used for this pupose (Dunn PM. Localization of the umbilical catheter by post-mortem measurement. Arch Dis Child 1966, 41: 69-75.)

UVCs and UACs 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 cather position determined by a Consultant Radiologist masked to treatment allocation on a chest and abdominal x-ray defined as:

UVC - catheter-tip between the upper border of T9 and the lower border of T10
UAC - catheter-tip between the upper border of T6 and the lower border of T10

Secondary outcome measures
1. Number of umbilical line insertions attempted and successful
2. Replacement or repositioning of umbilical line post confirmation x-ray
3. Total number of x-rays performed to confirm line position
4. Complications associated with UVC positioning in the liver
5. Pericardial effusions
6. Pericardial tamponade
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 lines in situ (days)
15. Catheter-related blood stream infection related to the umbilical line
16. Duration of hospital stay (days)
17. Death before discharge and at latest follow-up

Overall study start date
08/07/2012

Completion date
30/10/2013

Eligibility

Key inclusion criteria

1. Infants born at any gestational age at the National Maternity Hospital (NMH) who have umbilical catheter (umbilical venous catheter [UVC] and/or umbilical arterial catheter [UAC]) insertion attempted in the Neonatal Intensive Care Unit (NICU) are eligible for enrolment
2. Infants born outside the NMH and transferred after birth will be eligible for enrollment if they have not had umbilical catheterization at the referring hospital

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
101

Key exclusion criteria
1. Infants who have previously had a UVC or UAC inserted at a referring hospital
2. Infants with major congenital anomalies or hydrops that may alter the calculated or measured insertion length of the catheters or alter anatomy on x-ray (e.g. gastroschisis, exomphalos or congenital diaphragmatic hernia)

Date of first enrolment
08/07/2012

Date of final enrolment
30/10/2013

Locations

Countries of recruitment
Ireland

Study participating centre
The National Maternity Hospital
Dublin
Ireland
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Sponsor information

Organisation

The National Maternity Hospital (Ireland)

Sponsor details
c/o Dr Colm O'Donnell
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Sponsor type
Hospital/treatment centre

Website
http://www.nmh.ie/

ROR
https://ror.org/03jcxa214

Funder(s)

Funder type
Research organisation

Funder Name
The National Childrens Research Centre (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	01/01/2016		Yes	No