Incidence of migration and thrombus formation of umbilical venous catheters in infants

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Primary objective: to determine the incidence and location of thrombi in the umbilical venous catheter route during and after umbilical catheterization and in the same route in infants without umbilical catheters. Secondary objectives:A. to...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Neonatal and perinatal conditions
Study type	Observational non invasive

Summary

ID

NL-OMON43174

Source
ToetsingOnline

Brief title
MATCH

Condition

- Neonatal and perinatal conditions
- Embolism and thrombosis

Synonym
blood clot, thrombosis

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Infant, Migration, Thrombus formation, Umbilical venous catheter

Outcome measures

Primary outcome

The frequency of thrombus formation in the umbilical venous catheter route or

heart in infants with and without umbilical-vein catheters.

Secondary outcome

The amount of migrated umbilical venous catheters

The amount of umbilical venous catheters migrated to incorrect positions

The amount of umbilical venous catheters migrated to incorrect positions not

detected by the chest X-ray made as standard of care.

Study description

Background summary

Umbilical catheters are frequently required for the management of critically ill infants. Umbilical venous catheters (UVCs) are used for intravenous administration of parenteral nutrition, hypertonic solutions, blood products and medication.

Formation of thrombi is described as a possible complication in infants with umbilical venous catheters. The indication for treatment of these thrombi is controversial and different departments use different criteria. It is also possible that this thrombus formation, especially in the ductus venosus, is a physiological process and not pathologic. The ductus venosus is a fetal structure that after birth closes permanent with thrombosis and final fibrotic transformation of the vascular shunt into the ligamentum venosum.

Risk of formation of thrombi is increased in case of malposition of UVCs. Malposition of UVCs may also lead to other complications, such as hepatic necrosis, pericardial effusion and cardiac arrhythmias. The ideal location for umbilical-vein catheter-tips is at the junction between the inferior vena cava and the right atrium (IVC/RA-junction). The position of umbilical catheters is

checked by chest X-ray or ultrasound after umbilical catheterization and catheters are repositioned if necessary.

We clinically observed that UVCs after placement often migrate in the following days, despite fixation of the catheter with sutures in the umbilical cord and tapes to the abdominal wall. Although there is abundant amount of literature investigating the placement and location of the UVC, little is known about the migration after placement, how often this occurs, what are the risk factors, how much it migrates and whether the location of the tip is still acceptable. Migration may possibly lead to more complications.

Study objective

Primary objective: to determine the incidence and location of thrombi in the umbilical venous catheter route during and after umbilical catheterization and in the same route in infants without umbilical catheters.

Secondary objectives:
A. to investigate the frequency of migration of umbilical venous catheters in infants.
B. to identify risk factors for migration of umbilical venous catheters.

Study design

Prospective observational case-control study

Study burden and risks

The indication for chest X-ray will be set by the attending physician. Included infants are not exposed to extra radiation due to the study.
Cases will receive ultrasounds on day 1, 3, 7 and 14 after umbilical catheterization, the day of removing the catheter and whenever a chest X-ray is made on another day. Controls will receive ultrasounds on day 1, 7 and 14 after birth.
Ultrasound examination to identify the catheter and possible thrombus will take approximately 5 minutes. We do not expect infants to be harmed by this study, because ultrasonography is known to be safe, non-cumbersome and will be combined with other manipulations or examinations when possible. All premature infants on our department receive standard cerebral ultrasounds on day 1, 3 and 7 after birth and we will combine the ultrasounds for the study as much as possible with these cerebral ultrasounds.
Parents of participating infants may suffer from the incidental finding of asymptomatic thrombosis. In the counselling we will inform them about the possibility of these findings and the fact that thrombosis may be part of a physiological process and does not always need treatment. It is possible that infants will benefit from participation in the study because the results of the

ultrasound (more and more seen as the golden standard for verifying the position of umbilical-vein catheters) can be used above the results of the chest X-ray by the physician to make decisions about malposition of catheters. This study has to be conducted in this study population because this is the only population in which umbilical catheters are and can be used.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

* Study group: all infants receiving an umbilical venous catheter (case).
* Control group: For every included infant in the study group the next infant admitted to our ward without umbilical catheters (control).
* Matching case and control infants:
o For cases *30 weeks gestational age we will match a control with the same gestational age at birth (+/- 1 week).

o For cases < 30 weeks, matched controls are not available since all infants <30 weeks receive routinely umbilical catheters. For this group we will include infants without catheters with a gestational age of 30-32 weeks as controls.

Exclusion criteria

None

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	11-10-2016
Enrollment:	102
Type:	Actual

Ethics review

Approved WMO

Date:	08-09-2016
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL57948.058.16
Other	volgt