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

No registrations found.

| | |
|---|---|
| **Ethical review** | Not applicable |
| **Status** | Pending |
| **Health condition type** | - |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON28440

**Source**
Nationaal Trial Register

**Brief title**
MATCH

**Health condition**

Umbilical venous
Infant
Migration
Thrombus formation

Dutch:
Navelvenelijn
Pasgeborene
Migratie
Thrombusvorming

### Sponsors and support

**Primary sponsor:** Leiden University Medical Center
**Source(s) of monetary or material Support:** Leiden University Medical Center

## Intervention

## 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 and 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 venous catheters (UVCs) are frequently required for the management of critically ill infants. Formation of thrombi is described as a possible complication in infants with UVCs. 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.
Risk of formation of thrombi is increased in case of malposition of UVCs. 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 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.

In this prospective observational case-control study infants receiving UVCs are included as cases and infants without UVCs as controls. Serial ultrasound examination is performed to identify thrombi and their location and to identify the location of the tip of the catheter in infants with UVCs. We 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. We also investigate the frequency of migration of umbilical venous catheters in infants and identify risk factors for this migration.

**Study design**

See interventions

**Intervention**

Case: Ultrasound on day 1, 3, 7 and 14 of catheter, the day of removing the catheter and whenever a chest X-ray is made on another day.

Control: Ultrasound on day 1, 7 and 14 after birth (or day of discharge when between day 1 and 14).

# Contacts

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# Eligibility criteria

## Inclusion criteria

• Study group: all infants receiving an umbilical venous catheter will be included (case).

• Control group: For every included infant in the study group the next infant admitted to our ward without umbilical catheters will be included (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: | Parallel |
| Allocation: | Non-randomized controlled trial |

**Control:** N/A , unknown

## Recruitment

NL
Recruitment status: Pending

| | |
|---|---|
| Start date (anticipated): | 01-07-2016 |
| Enrollment: | 102 |
| Type: | Anticipated |

## Ethics review

Not applicable
Application type: Not applicable

## 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 |
|---|---|
| NTR-new | NL5713 |
| NTR-old | NTR5866 |
| Other | ABR-nummer : 57948 |

## Study results