

# Central Lines: Outcomes of Thrombosis and Sepsis study

ACTRN12611000070932

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|-------------------|---------------------------------|
| <b>Status</b>     | RECRUITING                      |
| <b>Phase</b>      | Phase 2, Phase 3                |
| <b>Sponsor</b>    | Women's and Children's Hospital |
| <b>Enrollment</b> | 100 participants                |

## Plain Language Summary

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Children in intensive care often have a central line — a tube placed into a large vein to deliver medications. These lines can sometimes cause dangerous blood clots. This study is testing whether giving a very low dose of heparin (a blood-thinning medication) through the central line prevents clots from forming, compared to saline (a saltwater solution with no active drug). Researchers use ultrasound to check for clots. The goal is to keep the line working safely and avoid serious complications.

You may be eligible if:

- You are a child between 0 and 18 years old
- You have a central venous catheter (CVC) that is expected to be in place for more than 24 hours
- You are admitted to a pediatric intensive care unit

You may NOT be eligible if:

- Your catheter was placed surgically (such as a Broviac or Hickman line) or is a subcutaneous port
- Your catheter is a peripherally inserted central catheter (PICC line)
- Your catheter is in the subclavian vein
- You have a known blood clotting disorder or are on anticoagulant medication (other than standard low-dose heparin for line maintenance)
- Your platelet count is very low (below 50,000)
- You already have a known blood clot in the affected vein
- You have a known allergy to heparin or have previously had heparin-induced low platelet counts

Talk to your doctor about whether this trial might be right for you.

## Key Eligibility Criteria

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### Inclusion (2)

- Children 0-18 years old
- Central venous catheter inserted and likely to be in place >24 hours

### Exclusion (8)

- CVCs inserted surgically e.g. Broviac or Hickman CVCs or subcutaneous ports.
- Percutaneously central catheters (PICC) inserted via a peripheral vein.
- Subclavian CVCs
- Patients with a known thrombophilia, coagulopathy (APTT (activated partial thromboplastin time)>50 s for >30 days old, >55 s for =30 days old ) or receiving anticoagulant medication, other than low dose heparin. For intravenous heparin, low dose means = 3 U/kg/hour, used to maintain CVC patency.
- Patients with a platelet count of <50 000 x 10<sup>9</sup> /L
- ... and 3 more (see full listing online)

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<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12611000070932>

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