

# Evaluation of efficacy, outcomes and safety of infant haemodialysis and ultrafiltration in clinical use: I-KID a stepped wedge cluster RCT

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**Primary conflicts of interest:** Malcolm Coulthard – possibility that eventually the successful marketing of the NIDUS® (Allmed, [www.allmedgroup.com](http://www.allmedgroup.com)) device could lead MC receiving a proportion of the royalties received from the manufacturer (Allmed) by the Newcastle upon Tyne Hospitals NHS Foundation Trust. David Grant – A member of the Global Network for Simulation in Healthcare Board. Rachel Agbeko – Editor for *The British Medical Journal* and supported by NIHR grants via substantive employer (NHS). Elaine McColl – NIHR CTU Standing Advisory Committee board membership from January 2015 to June 2016.

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## Plain language summary

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# Plain language summary

## Why do this study?

Some children in intensive care are so poorly that their kidneys do not work well, and they need help, called dialysis, to get rid of fluid and chemicals from their blood. For babies, we currently use peritoneal dialysis, where fluid is cycled in and out of the tummy, or adapted machines designed for bigger children (continuous veno-venous haemofiltration). A new machine, the NIDUS® (Allmed, [www.allmedgroup.com](http://www.allmedgroup.com)), was developed specifically for babies weighing under 8 kg with much smaller tubing. NIDUS worked well when studied in Newcastle but needed testing elsewhere.

## What was the question?

How well does NIDUS work compared to other dialysis methods? What are the problems?

## What did we do?

The study was done in six paediatric intensive care units who used their usual dialysis methods (=control) in the first part of the study and then later swapped to using the NIDUS (=intervention).

## What did we find?

We recruited 97 participants, 62 to control (49 peritoneal dialysis, 13 continuous veno-venous haemofiltration) and 35 intervention (NIDUS). We found NIDUS provided much better control of fluid removal. The CVVH machines were more efficient at blood cleaning than NIDUS, which was better than peritoneal dialysis.

## What does this mean?

We learnt a lot about babies needing kidney support in paediatric intensive care units and that all methods have advantages and disadvantages. We showed that NIDUS could be very useful for some participants because it cleans blood effectively and gives accurate, controllable fluid removal. We have gathered important information to help us improve NIDUS to make it easier to use and run. Many parents responded to our questionnaire and most told us they felt it was acceptable to be approached about taking part in research despite the circumstances. This is very important for future research studies.

We are very grateful to families for their generosity in becoming involved in this study.



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## This report

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