

Timing of Stoma Closure in Neonates: the ToSCiN mixed-methods study

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Disclaimer: This report contains transcripts of interviews conducted in the course of the research, or similar, and contains language which may offend some readers.

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Plain language summary

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Plain language summary

Babies who develop a bowel problem soon after birth may need surgical treatment and a stoma (where the bowel is brought out into a bag on the tummy). Stomas can be life-saving but can also cause problems. They must be 'closed' with a second operation once the baby has got better. The timing of this second operation varies between hospitals and we do not know the best time to do it.

To find out the best time to close a baby's stoma, we wanted to conduct a clinical trial. This would mean some babies having their stoma closed 'early', and other babies 'later' and seeing which group did better. Babies would be put into the 'early' or 'late' group at random so that we could have a fair comparison. Because doing a trial may be challenging, we first set out to find out if a trial would be feasible in the Timing of Stoma Closure in Neonates study.

What we did

- Found out what currently happens to babies with a stoma through a survey of healthcare staff and looking at data from several national databases.
- Collected data on 56 babies with stomas in 8 hospitals, including asking their doctors whether they would recruit these babies to a trial and when they would close their stoma.
- Interviewed parents of children who had had a stoma.
- Held focus groups with staff at the eight hospitals.
- Held a meeting for National Health Service staff and parents to discuss the way forwards.

What we found

- Parents and doctors think this question is important and that a clinical trial is a good idea.
- Deciding on the timing of stoma closure in the trial and what we mean by 'early' and 'late' is critical to the success of a trial. The timing may need to take into account that some babies born extremely preterm may be difficult to include.
- A trial that compares how well infants grow and/or length of stay in hospital between babies having early or later stoma closure may well be feasible.

What happens next

The National Institute for Health and Care Research (research arm of the Department of Health and Social Care) will use this to information to help decide if they would like to fund a trial in the future.

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