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Research Article

Designing a precision-medicine platform trial to improve the nutritional care and intestinal health of very preterm babies: the COLLABORATE study

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Plain language summary

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Plain language summary

The National Institute for Health and Care Research awarded us funding to develop an efficient way to test treatments to improve the care of sick and preterm newborn babies through a 'precision-medicine platform trial'. A platform trial is one in which we can test multiple interventions, and it is flexible so we can add and remove interventions from the trial over time. Not all infants will respond in the same way to any given intervention; the precision-medicine part of the trial allows us to work out in whom the interventions work best. We established a stakeholder collaboration and designed a unique research study to test multiple treatments to prevent and treat a serious disease, necrotising enterocolitis, which mainly affects very preterm babies and is a leading cause of death and long-term health difficulties. Necrotising enterocolitis is an infection of the gut that reduces the ability to digest milk, and hence can lead to problems with growth and development.

We consulted with parents, patients, and other stakeholders about the need for the study. We reviewed previous research and invited collaboration and suggestions for treatments that urgently need testing. We selected treatments to test first. These were chosen to find out whether pasteurised human donor milk, giving babies extra protein, or adding a probiotic (a type of healthy bacteria) in their feeds affects the risk of developing necrotising enterocolitis. In babies who need an operation for necrotising enterocolitis, we planned to test a new method to reduce the amount of gut removed (fluorescence-guided imaging) and medicines (insulin and arginine) to help the gut heal. We also developed studies to find out how the treatments affect gut and brain health. We used national data to design the study. We coproduced a video with parents and patients that explains the study. We will make our methods available to other researchers to test treatments for other diseases.

We submitted our proposal to the National Institute for Health and Care Research as a stage 1 application as required. However, this was unsuccessful with no opportunity provided to respond to panel comments or submit a revision.