An evaluation of the feasibility of conducting a randomised clinical trial to evaluate the clinical and cost-effectiveness of a more permissive temperature threshold for antipyretic intervention in critically ill children with fever due to infection: the FEVER feasibility study

Record Status
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Authors' objectives
A fever (high temperature) is a normal response by the body to infection. When a very sick child has a fever, the usual reaction from clinicians (doctors/nurses) is to cool down the child. This can be done using drugs, such as paracetamol, or using a cooling mat, sponging the child with water, etc. The temperature at which clinicians usually start these treatments is about 37.5°C. There is strong evidence, however, that fever may be an important bodily response and may actually help a child to recover from infection. In 2013, the National Institute for Health and Care Excellence (NICE) updated guidance for managing fever in children. It recommended that drugs should not be used only for the purpose of reducing a child's temperature. Most of the evidence for this recommendation came from research in non-critically ill children, therefore, it is unknown whether this recommendation should be applied to very sick children. Our aim is to compare giving treatments for fever at a higher temperature than usual, such as 39.5°C, with the usual temperature of around 37.5°C in children with infection admitted to an NHS paediatric intensive care unit (PICU). As large clinical trials are expensive, it is important to be confident that this trial can be done and that the different components of the trial can work together. Before starting a full trial, we will conduct an 18-month feasibility study. A feasibility study is research done before a full trial to answer the question can this trial be done? It is used to estimate important factors such as willingness of parents/children to take part. A pilot trial, part of this feasibility study, is a smaller version of the full trial and this is done to check that the different components all run smoothly. The first part of this study will involve conducting interviews with parents/legal guardians to understand whether the proposed trial is acceptable to them, how information should be written, what barriers they perceive to their child being included and what outcome measures are most important to them. We will discuss views on using deferred consent. Deferred consent is an approach which has successfully been used in previous emergency/critical care trials and involves including a child in a trial without prior consent from their parents/guardians and then seeking agreement later. The reason for considering this approach is that discussing a trial with parents/guardians when their child is in need of urgent treatment may be inappropriate and create an additional burden in an already very stressful situation. The second part will involve observing and collecting data on children with fever from infection in 20 PICUs. We will also collect data on the outcomes identified as important by parents/guardians. These data will be used to tell us how many children would need to take part in a full trial and which are best outcomes to use. The third part, the pilot trial, will be conducted in four PICUs and will recruit 100 children. We will test whether the deferred consent approach is acceptable to parents/guardians of participating children. This part will tell us, practically, if the trial can be done. We have patient representatives as co-investigators on this study. They are involved in developing how the study will be done, and in overseeing the conduct and management of this study. At the end, we will report a clear recommendation, or not, for continuation to a full trial.

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