

Restricted fluid bolus versus current practice in children with septic shock: the FiSh feasibility study and pilot RCT

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Plain English summary

The Fluids in Shock (FiSh) trial

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Plain English summary

Usual treatment when a child arrives at a hospital emergency department with a severe infection and shock is to give liberal amounts of fluid via an injection into a vein (fluid bolus therapy). However, this is based on weak evidence. A group of doctors and researchers came together and proposed the Fluids in Shock (FiSh) trial, which aimed to find out whether or not giving less fluid is beneficial.

Before a large trial is carried out, it is important to answer the question, 'can this trial be done?'. The FiSh feasibility study aimed to do this. First, we conducted an interview study asking parents for their views on the proposed trial and the acceptability of research without prior consent (RWPC), that is, delaying the research discussion and consent seeking until after their child has been given emergency trial treatments – an approach that has been used successfully in previous studies. Second, we conducted a pilot trial (a small version of the FiSh trial) to test important factors, such as number of children recruited and if doctors and nurses followed the trial protocol properly. Hospital staff and parents of children who participated in the pilot were interviewed for feedback.

In the initial interview study, the 21 parents interviewed supported both the FiSh trial and the use of RWPC. In the pilot trial, 75 children were recruited from 13 hospitals in England. Children were randomly allocated to receive either liberal (currently recommended volume) or smaller fluid boluses. Recruitment was close to the expected level (one patient per hospital per month) and hospitals usually gave the correct volume of fluid in each group. However, participants were a lot less sick than expected, with only a minority needing intensive care and most requiring only one fluid bolus to show improvement. Overall, parents and hospital staff supported the study.

Even though both the interview study and pilot trial were carried out successfully, because the children recruited were not as unwell as expected, the trial, as currently designed, is not feasible.

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