



Fluids in Shock (FiSh) Pilot Study

Participant Information Sheet (Site Research Staff)

We invite you to take part in a research study

You are being invited to take part in a research study. Please ask us if there is anything that is not clear in this information sheet or if you would like more information (contact details overleaf).

The aim of the FiSh trial will be to find out whether children with symptoms of septic shock should be treated with fluid boluses which are smaller (10 ml/kg) than currently recommended (20 ml/kg).

The FiSh Pilot Study is a small research study which is being done to inform the design of a larger FiSh trial, which we are hoping will occur in future. Before embarking on a large trial, it is important to assess whether it is possible to conduct such a trial. This study aims to gather that information, in terms of finding out if the trial procedures work smoothly and looking at the views of parents/legal representatives and the site research staff involved in screening, recruiting, randomising and consenting parents/legal representatives during the pilot randomised control trial (RCT).

Your hospital is one of 12 taking part in this study across the country.

Why have I been chosen?

As you are involved in recruiting children to research studies such as FiSh, your views are very important to us. We are asking trial recruiters from each of the FiSh Pilot Study sites to take part.

What will happen if I take part?

We will ask you to register interest in taking part in either a focus group or a telephone interview.

Focus groups will take place in a private meeting room at three selected hospital sites (<INSERT HOSPITAL NAMES>) towards the end of the pilot RCT recruitment period (months 7-8). Each focus group will take about 60-90 minutes and involve 8-10 site research staff. Individual telephone interviews will be arranged for up to 10 site research staff who register interest in taking part, but are unable to attend a focus group. Telephone interviews will take about 40-60 minutes.

All interviews and focus groups will be conducted by the University of Liverpool FiSh study team.

What will I be asked about?

We will ask you about the discussions you have had with families of children eligible to participate in the pilot RCT, including your thoughts on the consent process and your experience of explaining research without prior consent (deferred consent) to families. We will also ask you about what information families requested to help them make a decision about taking part in the pilot RCT. We are also interested in how you decided which children to approach for assent and any recommendations you have to inform the design of a future trial.

What are the possible benefits and risks of taking part?

This qualitative element of the study is very low risk. Should you want to discuss any aspect of the study, please contact Kerry Woolfall (details below).

Findings of this study will be used to inform the design of a future larger trial. We cannot promise that you or the families you work with will benefit directly from this study, but many people find that taking part in studies of this sort is useful because they have a chance to air their views and to reflect on things.

Who is involved in this study?

The National Institute for Health Research (NIHR) Health Technology Assessment (HTA) programme is funding the study. Dr David Inwald (Imperial College Healthcare NHS Trust) is the FiSh Study Chief Investigator. The study is sponsored by Imperial College Healthcare NHS Trust and is managed by the Intensive Care National Audit & Research Centre (ICNARC) Clinical Trials Unit. Dr Kerry Woolfall (University of Liverpool) is leading this component of the study.

What if there is a problem?

Any complaint about the conduct of this study, the way you have been dealt with during the study or any possible harm you might suffer will be addressed. If you have a concern about any aspect of this study, then you should speak to the researchers who will do their best to answer your questions (see contact details below). If you remain unhappy and wish to complain formally, then you can do this through the NHS Complaints Procedure. Details can be obtained from your employer.

How to contact us

If you have any questions, please contact:

Dr Caitlin O'Hara: Caitlin.O-Hara@liverpool.ac.uk Tel: 0151 795 5325 or

Dr Kerry Woolfall: K.Woolfall@liverpool.ac.uk Tel: 0151 794 4634

**Thank you for your time.
We are very grateful that you are considering taking part in this study.**