

Fluids in Shock (FiSh) Feasibility Study

Parent/Legal Representative Information Sheet

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We invite you to take part in research study

- Children are now much more likely to survive any serious infection than ever before. This progress comes from a whole package of treatments including antibiotics, infusions of fluid (e.g. saline solution) into a child's veins ("fluid bolus therapy") and support for breathing and heart function. We hope to improve survival further by refining one part of this package of treatment: by exploring *what is the best amount of fluid to give critically ill children in the earliest stages of care*.
- We are designing a clinical trial (called Fluids in Shock – FiSh) to find out whether giving less fluid bolus therapy to children with symptoms of a severe infection (septic shock) is better than giving a higher amount of fluid, as currently recommended.
- We would like to interview about 25 parents/legal representatives whose children have been admitted to hospital and treated for severe infection in the last three years.
- By speaking to parents/ legal representatives we hope to find out whether the trial is possible and, if so, how it should be done.
- The interview should take about 45 minutes and can be done over the telephone or at your home (if you live in North West England). Should you be interviewed, you will receive a £30 Amazon voucher to thank you for your time.

How to contact us

If you have any questions and/or would like to take part in an interview, please contact:

Dr Caitlin O'Hara
Telephone: 0151 795 5325
Email: Caitlin.O-Hara@liverpool.ac.uk

or

Lead Investigator – Dr Kerry Woolfall
Telephone: 0151 794 4634
Email: K.Woolfall@liverpool.ac.uk

Further information can be found on our website: www.icnarc.org/Fish
or Facebook page: www.facebook.com/FluidsinShock

1) Why are we doing this study?

Septic shock is a life-threatening condition that happens when a child's blood pressure drops to a dangerously low level due to a bacterial infection. Symptoms can include a high temperature, raised pulse rate, quick breathing and confusion. Previously healthy children may develop septic shock, sometimes very quickly. Some children have a higher risk than others, including those with a lowered immune system (e.g. due to leukaemia or chemotherapy) and those with various long-term medical problems.

Across the UK, children showing symptoms of septic shock are treated using fluid bolus therapy. Findings from a recent large African trial suggest that less fluid might be a better in treating children with septic shock than the amount currently recommended. However, further research is needed to find out which amount is best for treating septic shock in children.

Our aim is to find out whether children with symptoms of septic shock should be treated with less fluid (10 millilitres (ml) per kilogramme (kg)) than is currently given (20 ml per kg).

We are in the early stages of designing the FiSh Trial and would like to speak to parents/ legal representatives about what we plan to do to. The views of parents/guardians are important to help us find the best way to do the study, including how we should explain the study to parents/guardians and how we should seek consent when a child is very ill.

2) Who can take part?

We are looking for parents/ legal representatives whose child has been admitted to a hospital with severe infection within the last three years.

3) How can I take part?

If you would like to take part in a telephone interview, please contact Caitlin or Kerry by email or telephone (contact details are on the first page). If you live in North West England, you can choose to have an interview at your home instead.

Before the interview, we will send you a very brief information sheet (like this one) which will be used to invite parents/guardians to take part in the FiSh Feasibility Study.

During the interview, Caitlin will ask you what you think about the information sheet and what improvements you think we could make. We would also appreciate your views on the best way to speak to parents/guardians about this research and how best to seek consent in the challenging emergency setting. We would like to record the interview, but only with your permission.

After the interview, we will send you a £30 Amazon voucher to thank you for your time.

The views of parents/guardians of children who have experienced severe infection are very important to make sure we design this study in a way that is acceptable to parents/guardians and ensure that they understand the study information given to them in such stressful circumstances.

Taking part is completely optional and you can change your mind about being part of the study at any time by contacting the study team. If you are reading this in a hospital, your decision about whether or not to take part will not change the care of you or your family member in any way.

If you have any questions before deciding to take part, please do not hesitate to contact us. The study results will be made available on the study website when the study is finished.

4) Who is involved in this study?

The National Institute for Health Research (NIHR) Health Technology Assessment (HTA) programme is funding the study. The study has been reviewed by the NIHR HTA and the North West – Liverpool Central Research Ethics Committee (15/NW/0913), who have agreed that the study is being conducted in a correct and appropriate manner. Dr David Inwald (Imperial College Healthcare NHS Trust) is the FiSh Study Chief Investigator. Dr Kerry Woolfall (University of Liverpool) is leading this Feasibility Study. The FiSh research team are qualified to do this study because they have all the specialties and skills needed. Members of team have a lot of experience in caring for children with septic shock and are very active in health research. Parents of children who have experienced septic shock have been involved in the development of this study.

5) What if there is a problem?

Complaints: Imperial College Healthcare NHS Trust holds standard NHS Hospital Indemnity and insurance cover with NHS Litigation Authority for NHS Trusts in England, which apply to this study. If you experience serious and enduring harm or injury as a result of taking part in this study, you may be eligible to claim compensation without having to prove that Imperial College Healthcare NHS Trust is at fault. This does not affect your legal rights to seek compensation. If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the Chief Investigator. The normal National Health Service complaints mechanisms are also available to you. If you are still not satisfied with the response, you may contact the AHSC Joint Research Compliance Office, telephone: +44 (0)20 7589 5111.

For NHS service advice or support please contact: Patient Advice and Liaison Services (PALS) services. Go to <http://www.nhs.uk/> to find your local PALS contact details. For support on any other issue please contact: The Samaritans. Website: <http://www.samaritans.org> telephone: 116 123. There are also a range of support groups for parents whose child has experienced severe infection. Some of these include:

- UK Sepsis Trust. Website: <http://sepsistrust.org> telephone: 0845 606 6255
- Meningitis Research Foundation. Website: <http://www.meningitis.org/> telephone: 080 8800 3344
- Children with Cancer UK. website: <http://www.childrenwithcancer.org.uk/care> telephone: 020 7404 0808