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Fluids in Shock (FiSh) Pilot Study

Participant Information Sheet (Parent/Guardian)

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How to contact us

If you have any questions please contact:

Research Nurse
Name: ***Name***
Telephone: ***Number***

Principal Investigator
Name: ***Name***
Telephone: ***Number***

We invite you to provide consent for your child's information to be included in a research study

Although we appreciate that this is a very difficult time for you and your family, we would like to ask you to spend a few minutes deciding on whether or not you would consent for your child's information to be included in a research study, which is aiming to improve the treatment of children with severe infection in future.

Your child was admitted to hospital with a severe infection (septic shock). A whole package of treatments are currently used to treat children with severe infections including antibiotics, multiple rapid doses (boluses) of fluid (e.g. saline solution) into a child's veins (this is called fluid bolus therapy) and support for breathing and heart function. We hope to improve the outcome for children with severe infection by refining one part of this package: by exploring *what is the best amount of fluid to give in the earliest stages of treatment*.

The FiSh Pilot Study is a small research study which is being done to inform the design of a future larger study (clinical trial). Before embarking on a large clinical 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 and staff involved in the trial.

Before you decide if you want to give your permission for your child's information to be included in this study, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully. Discuss it with friends and relatives if you wish. You are free to decide whether or not you wish for your child's information to be included. Please ask the nurse or doctor who has spoken or written to you about this study if there is anything that is not clear or if you would like more information.

Important things that you need to know

- Your child was showing signs of a severe infection called 'septic shock'.
- Across the UK, children with septic shock are treated by injecting multiple doses (boluses) of fluid (e.g. saline solution) quickly into a vein. This is called 'fluid bolus therapy'. The best amount of fluid to give per bolus is not known. One recent large research study suggested that using less fluid than the amount currently recommended might be better, but further research is needed.
- We want to find out whether giving children fluid boluses of 10 ml per kg (about 2 spoonfuls per kilogram in weight) is better than the amount currently recommended (20 ml per kg).
- As this was a medical emergency, there was no time to delay your child's treatment by asking for your consent. Your child was given an initial 20 ml per kg of fluid and then entered into the study. Your child was then given boluses of either 10 ml or 20 ml per kg.
- This is called 'research without prior consent'. This kind of research is done in emergency situations when two forms of treatment are being compared to find out which is the best treatment.
- We are now asking for your consent for your child's information to be included in the FiSh Pilot Study.

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 an infection. In the UK, children showing symptoms of septic shock are treated using fluid bolus therapy. Current recommendations are to use 20 ml per kg per fluid bolus; however this recommendation is based on very limited previous research, which did not involve any large scale clinical trials.

Recently, a very large trial called FEAST (Fluid Expansion as Supportive Therapy) was conducted in Africa, which looked at the use of fluid therapy in severe infection. FEAST involved 3000 children and showed that using less fluid (i.e. smaller amounts per bolus) resulted in fewer deaths. However, FEAST was conducted in very poor countries in which many supportive treatments, which are routinely given in richer countries, were not available. Thus, it is not clear if the same results would be seen in a richer country like the UK. Further research is needed to find out which amount of fluid bolus therapy is best at treating children with septic shock in the UK and until that is done, the current treatment recommendations cannot be changed.

Our aim is to find out whether children with symptoms of septic shock should be treated with fluid boluses which are smaller (10 ml per kg) than currently recommended (20 ml per kg). This hospital is one of 13 that are taking part in this study across the country. The study will involve approximately 108 children and young people.

This study is a pilot study – in other words, it is being done to inform the design of a larger study (a clinical trial) which we plan to run in hospitals across the UK.

2) What do I need to know about the treatments used and possible benefits and risks?

Children arriving at emergency departments with septic shock across the UK are given fluid bolus therapy very quickly as part of their emergency treatment. Fluid bolus therapy helps improve the circulation of blood around the body. This, in combination with other treatments, is thought to give them the best chance of recovery

The risks of fluid bolus therapy are well known and include fluid on the lungs (pulmonary oedema) and elsewhere in the body. The clinical and research teams carefully monitored your child for these and other risks as they would with any child with septic shock. Your child also received all other usual emergency treatments necessary to give the best chance of recovery.

We cannot promise that your child benefited directly by participating in this study. The benefits and risks of receiving 10 ml per kg per fluid bolus instead of 20 ml per kg are unclear at this time – which is why this research is needed. Ultimately this study will help to improve the future treatment of children with septic shock.

3) How was it decided which fluid amount my child received?

The FiSh Pilot Study is a randomised controlled trial, which means that each child is randomly put into one of two groups (children allocated to group 1 receive 20 ml per kg per fluid bolus, and children allocated to group 2 receive 10 ml per kg per fluid bolus). To make it fair, the groups are randomly selected by a computer programme. Your child had an equal chance of receiving either 10 ml per kg or 20 ml per kg per fluid bolus.

Upon arrival into hospital and before being entered into the study, your child received one 20 ml per kg fluid bolus as part of usual emergency treatment. Your child would only then have been entered into the study if the clinical team looking after them thought that further fluid bolus therapy was necessary. After being entered into the study, your child was then given fluid boluses of either 10 or 20 ml per kg until signs of shock resolved or until there were signs that no more fluid should be given. In both groups, boluses were administered every 15 minutes.

4) Why am I being asked *after* my child has been given the treatment rather than before?

As this was a medical emergency, we could not delay giving the fluid boluses your child needed. Explaining the study to you in advance would have caused a delay in giving your child urgent treatment. We are now asking for your permission to collect information for the study about your child's hospital stay. This is called 'research without prior consent' – a method of consent which has been used in other emergency studies. We would also like to know your views on the study. This information will help the FiSh study team find out how best to run a larger research study in future.

5) What will happen next?

1. If you agree for your child's information to be included in the study, the hospital research team will collect anonymised information about your child's hospital stay, which will be sent to the Intensive Care National Audit & Research Centre (ICNARC) where it will be held securely. The anonymised information collected will be retained for five years following the end of the study – after which it will be securely destroyed. Even if you agree, **you can change your mind** at any time and can contact the research team using the contact details on the first page of this sheet.

2. Whether you do or do not agree for your child's information to be in the study, we are also interested in your views on the consent process for this study. This will involve taking part in a telephone interview (30-60 minutes) with a member of the FiSh study team. You will be asked about how you felt about the study consent process, why you did or did not provide consent and how you think consent should be sought if we run a larger study. 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 has died. If you take part in a telephone interview, upon completion you will be sent a £20 Amazon voucher to thank you for your time.

If you would like to help, we ask that you complete the relevant sections of the consent form and provide your contact details. A member of the FiSh study team will then contact you within the next four weeks to arrange an interview. The anonymised data collected from the telephone interview will be retained for five years following the end of the study – after which it will be securely destroyed. Audio recordings of the telephone interviews will be destroyed once transcribed.

3. Data collected from research studies can be used to address many important research questions beyond those planned in the original study. This has the potential to provide real benefit to patients and the scientific community. If possible, we would like your permission to share anonymised data collected from the study if we feel it could contribute to answering other important health questions after your child's participation in FiSh. Examples of data would include your child's age, their condition (e.g. sepsis), what treatments they were given and how long they were in hospital. Any data would be fully anonymised prior to being published or shared with other researchers. **If you do not agree**, your child's information will only be included in the FiSh Pilot Study (if agreed).

We are also interested in your permission to contact you about any future related research studies where we feel your views and opinions would be valuable (for example, to take part in an interview discussing a new research study related to infection in children). If you would like to help, we ask that you complete the relevant sections of the consent form and provide your contact details. Your details will be kept for up to 12 months after the study has ended.

The study results will be made available on the ICNARC website (www.icnarc.org) when it is finished.

6) Who is involved in this study?

The study is being run in 13 hospitals across the country. 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 Pilot Study Chief Investigator. The study is sponsored by Imperial College Healthcare NHS Trust and is managed by ICNARC. Parents of children who have experienced septic shock have been involved in the development of this study, including this information sheet and how you were asked to take part.

7) What if there is a problem?

Complaints: If you have a concern about any aspect of the FiSh Pilot Study, you should ask to speak with the hospital research team (contact details are on the first page) who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure – details can be obtained from your child's hospital.

Harm: 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 your child is proven to have been harmed 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 Principal Investigator. The normal NHS complaints mechanisms are also available to you. If you are still not satisfied with the response, you may contact the Imperial AHSC Joint Research Compliance Office (telephone: +44 (0)20 7589 5111).

For NHS service advice or support, please visit http://www.nhs.uk/ to find your local Patient Advice and Liaison Services (PALS) services contact details.

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

There are a number of support groups for anyone who has been affected by the death of child, including:

Sands (Still birth and neonatal death charity)
Website: https://www.uk-sands.org/
Telephone: 020 7436 5881

Child Bereavement UK
Website: http://www.childbereavementuk.org/
Telephone: 0800 02 888 40

8) Who has reviewed the study?

The study has been reviewed by the NIHR HTA, the Health Research Authority and the London - Stanmore Research Ethics Committee (Reference: 16/LO/0854), who have agreed that the study is being conducted in a correct and appropriate manner.

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