

IRAS Number: 195544



Fluids in Shock (FiSh)

A study about giving different amounts of fluid to children and young people with severe infection

Introduction

We are doing this research study to find out the best way of treating children and young people who have a severe infection (known as septic shock).

Why are we doing this research?

This is a pilot study – it aims to answer the question: is it possible to conduct a large research study comparing giving two different amounts of fluid to treat sick children and young people with septic shock?

Septic shock is a life-threatening condition that happens when a person's blood pressure drops to a dangerously low level due to bacterial infection. Across the UK, children showing symptoms of septic shock are treated using fluid bolus therapy – infusions of fluid (e.g. salt solution) into a child's vein. Findings from a recent large African research study suggest that less fluid might be better in treating children with septic shock than the amount currently given. However, further research is needed to find out which amount is best at treating septic shock in children.

We want to find out whether children and young people with symptoms of septic shock should be treated with less fluid (10 millilitres (ml) per kilogram (kg)) than is normally given (20 ml per kg).

Before embarking on a large research study comparing the two different fluid amounts, it is important that we first understand whether it is possible to conduct such a study. This pilot study aims to gather that information, in terms of whether we can recruit sufficient numbers of children and young people and whether the planned research procedures will work smoothly.

Why were my parents/guardians asked if I could take part in the study?

When you arrived in hospital, you were showing symptoms of septic shock and needed treatment, including fluid bolus therapy. You were then entered into the study and given either 10ml per kg or

20ml per kg. There was no time initially to discuss this with your parents but it was explained to them as soon as possible afterwards. We were not able to ask you about the study at the time because you were so unwell. About 100 other children and young people will be taking part.

If you have any questions about the research or taking part in the study, you can ask your Mum or Dad, or one of the nurses.

What happened as part of the study?

You were put into one of two groups:

- ★ **Group 1:** if you are in this group, you would have been given 20 ml per kg fluid boluses, the normally given fluid amount. You would have been given the fluid through a plastic tube and needle into a vein so that the fluid would go into your blood stream.
- ★ **Group 2:** if you are in this group, you would have been given 10 ml per kg fluid boluses or half the normally given fluid amount. You would have been given the fluid through a plastic tube and needle into a vein so that the fluid would go into your blood stream.

A computer decided at random which group you would be in. There was an equal chance that you would be in each group; your parents/guardians weren't allowed to pick which group you went in. This makes it a fair test. It doesn't matter which group you are in, you will always get the best possible care.

We collected some information about your stay in the hospital to be able to compare the two groups.

What are the possible benefits of taking part?

You are playing an important part in finding out what is the best way to help young people like you to get better. We can't promise this research will help you, but you will be helping others just like you who have the same problems in the future.

What happens when the research stops?

When we have collected information from everyone, we will tell you and your family what we found out.

Will anyone else know I am doing this?

No. All of your information will be kept strictly confidential and only people working on the study will be allowed to see it.

Thank you for reading this leaflet

