[To go on your hospital Trust's Headed paper]

ProMISe

Patient Information Sheet - short

Protocolised Management In Sepsis (ProMISe): a multi-centre, randomised controlled trial of the clinical and cost-effectiveness of early, goal-directed, protocolised resuscitation for emerging septic shock

Introduction

When a person has a severe infection, their body may react by producing an 'inflammatory response', which can damage important organs, such as the heart and lungs to the point where they no longer function properly. When infection causes organ failure, it is called severe sepsis. If severe sepsis results in low blood pressure, it is referred to as septic shock. The usual resuscitation for severe sepsis in the United Kingdom involves treatment with antibiotics, fluids given into a vein, and medication to support the blood pressure, the heart and lung function. In the United States, a small trial performed at one hospital found that usual resuscitation for severe sepsis worked better with a treatment plan guided by central blood oxygen levels during the first six hours of hospital treatment. This treatment plan is early, goal-directed, protocolised resuscitation. This trial only involved a small number of people and more research is needed.

What is the purpose of the ProMISe trial?

We would like you to take part in a clinical trial to investigate whether early, goal-directed, protocolised resuscitation results in more people recovering from severe sepsis or septic shock when compared with usual resuscitation. Early, goal-directed, protocolised resuscitation is a structured series of steps or elements that must be initiated as soon as possible, and completed over a six-hour period. Usual resuscitation is less structured in that the doctor may provide some of the same elements, but does not necessarily follow a structured series of steps or elements in a time dependent manner.

Why have I been asked to take part in the trial?

You are eligible to participate in this trial because you have severe sepsis or septic shock, and have been admitted through the Emergency Department in your hospital. Joining the trial is entirely

voluntary. Once you have read this information sheet, if you agree to take part, we will ask you to sign a consent form. You are free to withdraw at any time, without giving a reason, and this will no affect the standard of care you receive.

What will happen to me if I take part?

In order to find out which of the resuscitation methods is best, each patient will be randomly put into one of two groups (early, goal-directed, protocolised resuscitation or usual resuscitation) – as i tossing a coin. The results will be compared to see which one is better. There is equal likelihood that you will receive either early, goal-directed, protocolised resuscitation or usual resuscitation. Neither you nor the doctor can decide which resuscitation method you will receive. Whether you receive early, goal-directed, protocolised resuscitation or usual resuscitation (details below), you will be provided with all other standard care as necessary, such as antibiotics or surgery. We will collect information about your progress throughout your hospital stay.

- **Early, goal-directed, protocolised resuscitation:** you will receive resuscitation which follows the trial protocol for six hours. All patients will have a specialised central venous catheter (CVC) placed into a large vein, usually in the neck, to measure the oxygen level in the blood. These levels are monitored and treated accordingly. This specialised CVC is used routinely. You may also have an arterial catheter (a small tube) inserted into an artery in your wrist or groin to monitor blood pressure. Once a total of six hours of early, goal-directed, protocolised resuscitation has been completed, you will be given standard care at the discretion of the treating clinician(s) in accordance with current best practice.

- **Usual resuscitation**: you will continue to be monitored and treated by the hospital's usual clinical team in accordance with the hospital's current standard resuscitation practice. You may have a CVC and an arterial catheter inserted if the treating clinician(s) deems this is needed for your treatment.

What are the possible disadvantages and risks of taking part?

All medical procedures, regardless of trial participation, involve some risk of injury. In addition, there may be risks associated with this trial that are presently unknown or unforeseeable.

- **CVC complications:** the most common complication is infection which occurs in less than one in 20 patients. The most serious complications are puncture of the lung, causing collection of air into the chest, or puncture of an artery causing blood to collect in the chest. These are rare and occur in less than one in a hundred patients. Other complications include injury to the blood vessel causing bruising and/ or bleeding or a blood clot inside the blood vessel (thrombosis). These are treatable and all patients will be assessed for the presence of any of these complications.

- **Arterial catheter complications:** these are rare, but may include bleeding, infection or a lack of blood flow to tissues supplied by the artery, which is nearly always correctable by removal of the catheter.

What are the possible benefits of taking part?

We cannot promise that participation in the trial will benefit you during your hospital stay but the information we get from this trial may help improve the way in which we care for patients with severe sepsis or septic shock in the future.

What if something goes wrong?

If you are harmed due to someone's negligence or wish to complain about any aspect of the way you have been approached or treated during the course of this trial, contact the Hospital's Patient Advice & Liaison Service (PALS) for further information.

Who has reviewed the trial?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This trial has been reviewed and given a favourable opinion by the North West London Research Ethics Committee 1.

Please also read the ProMISe Patient Information Sheet which has more detailed information about the ProMISe Trial.