

Short Participant Information Sheet

Purpose

This is a guide to the information to be provided to the patient if they indicate they may be willing to take part in this research study in order that they may give verbal consent to take part.

The provision of the information and the agreement from the patient to take part must be witnessed by another member of staff in the Emergency Department.

If the patient consents to take part in the study this form should be signed by the person providing the information to the patient.

Invite the patient to take part in the research study investigating whether early treatment with vasopressors is better than standard fluids used today.

Why are they being asked to take part?

- You have been asked to take part as you have been diagnosed with signs and symptoms of an infection (sepsis).
- The decision to take part is voluntary. You do not have to consent to being in this study to be treated for your infection. If you decide not to take part in this study then you will receive standard care.

What is the aim of the study?

- We are looking at comparing two different methods of treating sepsis. The standard care is to give IV fluids through a drip in your arm then adding a vasopressor medication. Vasopressors increases the blood pressure which allows a better blood flow to your vital organs. The alternative approach is to give the vasopressor medication straight away.

What will happen to me?

If you take part in the study, you will be assigned to one of two treatment groups at random (like tossing a coin).

- **Treatment 1 – Usual Treatment**

You will be given the normal treatment used by this hospital for treating infections – a salt solution (balanced crystalloid) solution via a drip. You may have medication to increase your blood pressure (vasopressors) added at a later point, depending on your condition.

The medicine used in the intervention arm (norepinephrine) may harm an unborn child and women who are pregnant will not be able to take part in the study. A pregnancy test will be performed before any study treatment is administered in all women who could become pregnant. This includes women who routinely use contraception such as the combined oral contraceptive pill, have an intrauterine device (sometimes known as a 'coil') or who abstain from sexual intercourse.

- **Treatment 2 - Intervention**

You will have the medication to increase the blood flow to your vital organs (vasopressors) started immediately, via a drip in your arm. You may be given extra salt solution fluid through the drip in your arm later, if required.

- Each treatment will be given for as long as required, but participation in the trial and collection of data about you will stop at 48 hours. All other treatment will be decided by the doctor treating you, after discussing with you.
- Once you leave the hospital we will look at your medical records 30 and 180 days later to see how well you have recovered and if you have been back to hospital for any further tests or treatment. We won't need to contact you again to do this.
- You will not need to come to hospital for any additional visits.

What are the possible risks?

- The risks of this clinical trial include many of the same risks that are associated with routine treatment of sepsis.
- Risks that could occur with study treatment are:
 - Headache (mild)
 - Shortness of breath (mild)
 - Irregular heart rate (rare)
 - Inflammation of infusion site

Do I need to take part?

- No you are free to withdraw your consent from the study at any time and your health care will not be affected in any way.

What are the benefits of taking part?

- Being in this study may be of no direct benefit to you but others may benefit from the results of this research in future.

Additional Blood Tests

- ~~• We ask that you provide 3 additional blood samples which we aim to obtain while collecting your routine blood samples. Consent to the additional blood samples is optional and there will also be optional consent to give permission for blood samples to be retained for future use. These samples will be analysed for markers of inflammation, immune system function and genetic analysis. The blood samples will be shipped to the laboratory in Edinburgh in a coded fashion whereby only the research site will have access to the document that links participant codes with personal identifiable information.~~

Will my taking part in this study be kept confidential?

- Yes. Your personal health information, including your medical data will be collected by the study doctor and other site staff for this study's research purposes and every effort will be made to ensure it is kept confidential.

What if something goes wrong?

- The normal National Health Service Complaints mechanisms will be available to you.

- There are no payments made to participants
- There will be no compensation for you or your insurance company in the event of an injury

More detailed information about this study will be provided in a separate information and consent form that you will be asked to read and sign after your condition has stabilised, if you agree to continue with the study.

Contact your study doctor for questions about the research or injuries from the research at the number on the front of this form.

SIGNATURES

I confirm that information about this study was explained to the patient, and any questions they had about this were answered. They agreed to take part in and consent to the procedures required by the above study, and were informed that relevant sections of their medical notes and data collected during the study, may be looked at by individuals from Greater Glasgow & Clyde (Sponsor), from regulatory authorities, or from the NHS hospital, where it is relevant to their taking part in this research. They gave permission for these individuals to have access to their records.

Patient Name (please print)

Date

Name of person taking

Signature

Date

Consent (please print)