



EVIS
PIS ICF ~~v1.3-v1.4~~ 03 Nov ~~17~~
~~Jun~~ 2022
Professional Rep
(England, Wales & NI)
IRAS ID: 307862

Participant Information Sheet

Professional Legal Representative (England, Wales & NI)

You are invited to consider giving your permission for your patient to take part in a research study as we have been unable to contact a relative, welfare attorney or guardian for them despite our best efforts. To help you decide whether or not your patient should take part, it is important for you to understand why the research is being done and what it will involve. It may be the case that your patient has already been entered into the study with the agreement of one of the doctors treating them to prevent any delay to their treatment starting. This was only done after our best efforts to contact you were not successful. If this was the case, we will discuss with you what has already happened and whether you give your permission for them to stay in the study. The information below would have been given to you if you were available at the time. Please take the time to read the following information carefully. Talk to others about the study if you wish. Contact us if there is anything that is not clear, or if you would like more information. Take time to decide whether or not you wish for your patient to take part.

Purpose of the Study

Sepsis is a life-threatening reaction to an infection. It happens when the immune system overreacts to an infection and starts to damage the body's tissues and organs.

The aim of this research study is to compare the two different ways to treat sepsis, in the early phase of treatment immediately after your patient arrived in hospital. The standard approach is to give a salt solution fluid through a drip in their arm to start with, then later adding in a medication that increases the blood flow to their vital organs (a vasopressor medication called norepinephrine) if required. The alternative approach is to start the vasopressor medication immediately, and then later add in extra salt solution fluid via a drip if required. Vasopressors work by increasing the blood pressure which allows a better blood flow to their internal organs. We plan to see which approach is better and to see if they have a role in improving a patient's recovery time, reducing complications, the length of time they stay in hospital and longer term poor health.

Based on research that has already been done, we believe treating patients with vasopressors when they arrive in the Emergency Department, may have potential advantages over the standard fluids used today. However, the evidence is not clear and that is why we are doing this research.

Why has this patient been invited to take part?

This patient has been asked to take part as they have been diagnosed with signs and symptoms of an infection (sepsis).

However, they currently lack the capacity to make an informed decision about whether they can take part in a research study and they do not currently have a relative available in person or by phone/video-call to give consent on their behalf. We are therefore asking you as their treating clinician if you will give consent on their behalf to join the study. This is permissible under the Mental Capacity Act 2000.

Does this patient have to take part?

No, it is up to you to decide whether or not they take part in the research or not. If you decide your patient should take part you are still free to change your mind at any time and without giving a reason. Deciding not to take part or withdrawing your patient from the study will not affect the healthcare that they receive now or at any stage in the future.

What will happen to this patient if they take part?

A member of the research team will speak to you to discuss this patient's participation in this study and make sure you understand everything. We will give you time to decide if you are happy for them to take part. At most this could be up to 30-40 minutes but may only be 10-15 minutes if you feel happy to make a decision. This is to make sure there is no delay to this patient's treatment starting. You will then be asked to give written consent. We will review this patient's medical notes including medical history, blood tests, other tests they may have had and any other treatment.

If this patient takes part in the study they will be put at random (like tossing a coin) into one of two treatment groups:

Treatment 1 – Usual Treatment

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

Treatment 2 - Intervention

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

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 contraceptives such as the combined oral contraceptive pill, have an intrauterine device (sometimes known as a 'coil') or who abstain from sexual intercourse.

For Treatment 1 and Treatment 2

Each treatment will be given for as long as they are required, but participation in the trial and collection of data about them will stop at 48 hours. All other treatment will be decided by the doctor treating the patient.

Once the patient leaves the hospital we will look at their medical records 30 and 90 days later to see how well they have recovered and if they have been back to hospital for any further tests or treatment. We won't need to contact the patient again to do this.

Taking part in the study should not cause much inconvenience to the patient other than having to answer some additional questions about their health and completing a questionnaire. We will contact them to complete a short questionnaire 30 days and 180 days after the start of their study treatment. The questionnaire takes less than 5 minutes to complete.

They will not need to come to hospital for any additional visits.

What are the possible benefits of taking part?

There is no guarantee that this patient will receive any benefit from this study but the results from this study might help to improve the healthcare of future patients with sepsis.

What are the possible disadvantages of taking part?

It is not thought that there are many disadvantages to taking part in this study, however as with any treatment there are some risks. Occasionally when patients have vasopressors they develop mild reactions such as a headache or shortness of breath. These reactions normally disappear when the drip is slowed down or stopped. With any intravenous infusion there is also a risk of fluid leaking into the skin, this can cause temporary inflammation and irritation at the surrounding tissue/skin. Evidence suggests that this occurs in about 3% of patients. Your patient's infusion site will be checked regularly by a healthcare professional to prevent any leaking. Another rare side effect of vasopressors is patients may experience an irregular heart rate however your patient will be closely monitored by the clinical care team to monitor any side effects.

Additional Blood Tests

~~Your patient may be asked to give three additional blood samples. Consent to the additional samples is optional and there will also be optional consent to give permission for blood samples to be retained for future use. The doctor taking consent will be able to tell you if this is an option. Each sample is around 15ml (three teaspoons) and will be taken in the first 48 hours of the study. Where possible these blood samples will be taken with routine samples to minimise the inconvenience/discomfort to your relative. The blood samples will be analysed for markers of inflammation and immune system function along with genetic analysis. The blood samples will be shipped to the laboratory 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 patients' participation in the study be kept confidential?

Yes. NHS Greater Glasgow & Clyde is the sponsor for this study based in the United Kingdom. We will be using information about this patient and their medical records in order to undertake this study and will act as the Data Controller for this study. This means that we are responsible for looking after this patient's information and using it properly. NHS Greater Glasgow & Clyde will keep non-identifiable information about this patient for 20 years after the study has ended.

Your rights to access, change or move this patient's information are limited, as we need to manage the information in specific ways in order for the research to be reliable and accurate. If you withdraw this patient from the study, we will keep the information about them that we have already obtained. To safeguard the patient's rights, we will use minimally personally identifiable information possible.

You can find out more about how we use patient's information by contacting the Data Protection Team – 0141 355 2059 or email data.protection@ggc.scot.nhs.uk



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[NHS/other site] will keep the patient's name, [NHS number] and contact details [add other identifiers] confidential and will not pass any of this information other than a copy of the consent form, which confirms that you agreed for this patient to take part in the study. This will only be looked at by an authorised member of the Study Monitoring team.

[NHS/other site] will use this information as needed, to contact the patient about the research study, and make sure relevant information about the study is recorded for the patient's care, and to oversee the quality of the study. Certain individuals from NHS Greater Glasgow & Clyde and/or regulatory authorities may look at the patient's medical and research records to check the accuracy of the research study. NHS Greater Glasgow & Clyde will only receive information without any identifying information. The people who will analyse the data gathered from this study will not be able to identify the patient and will not be able to find out their name, [NHS number] or contact details.

[NHS/other site] will keep identifiable information about the patient from this study for 10 years after the study has finished.

All data gathered during the study will be coded by a unique identified meaning that all of the patient's personal details will be removed. We will record the patient's participation in the patient's medical record so that other doctors involved in the patient's care will be aware. All information obtained for the study will also be entered into a secure computer server which is located at our expert data centre.

If you chose to consent to long term follow up about your patient's future wellbeing by data linkage NHS Greater Glasgow & Clyde will ~~share~~ **provide** your patient's personal information ([NHS/CHI number, postcode, date of birth, sex at birth](#)) to NHS departments (such as NHS digital in England and [the electronic Data Research and Innovation Service \(eDRIS in Scotland\)](#))~~to NHS departments~~ to allow them to provide information on your patient's health status. We would also like to let your patient know about other research studies that may be of interest to your patient and will ask your permission to contact your patient about them. These studies would be subject to funding and regulatory approvals and your consent for this is optional. If you chose to consent for your patient to be contacted about future research studies your patient's personal information will be used by NHS Greater Glasgow & Clyde to facilitate this. Any personal information provided for long term record linkage or contact about future research will be stored securely, kept strictly confidential and processed in accordance with the EU General Data Protection Regulation (GDPR) (2018).

We also ask that we can inform the patient's GP of their participation in the study

What if there are any problems?

If you have a concern about any aspect of this study please contact a member of the research team (contact details below) who will do their best to answer any questions.

If you have a concern about any aspect of the study, you can speak to the study doctor who will do their best to answer any questions. If you remain unhappy and wish to complain formally you can do this by contacting the chief investigator – Dr Alasdair Corfield Alasdair.corfield@ggc.scot.nhs.uk

The normal National Health Service Complaints mechanisms are available if you have any concerns or wish to complain. Tel: 0141 201 4500 email: complaints@ggc.scot.nhs.uk



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In the unlikely event that something goes wrong and your patient is harmed during the research and this is due to someone's negligence then you may have grounds for legal action for compensation against **[insert health board]** but your patient may have to their your legal costs.

What will happen if I don't want my patient to carry on with the study?

Your patients' participation is entirely voluntary. You can withdraw them from the study at any time (prior to them giving their own consent) without giving a reason, without their medical care or legal rights being affected.

If you withdraw them from the study, the information which has been collected about them whilst they have been in the study can be used as part of the results of the trial. If you chose to stop participating in the trial we will ask you if you are happy for the data we have collected so far can be used

What happens when the study is finished?

All the data collected will be kept securely for 10 years after the study has finished in case it needs to be reviewed again. At the end of the study we will make the study data available for other researchers to look at. Before we make it available we will make sure it doesn't contain any data which could be used to identify your patient.

What will happen to the results of the study?

This study will be written up and submitted for publication in a medical journal. It is likely that the results will also be presented at academic meetings or conferences. Once the study has been published a summary of the findings will be made available. Your patient will not be identified in any published results. You or your patient can contact their local study team to find out the final results if they wish

Who is organising and funding the research?

The study is sponsored by NHS Greater Glasgow & Clyde and will be coordinated by the Project Management Unit. This study has been funded by the National Institute for Health Research.

Who has reviewed the study?

The study has been reviewed by an independent group of people called a Research Committee to protect your safety, rights, wellbeing and dignity. A favourable ethical opinion has been obtained by the Scotland A Research Ethics Service. The Medicines and Healthcare Products Regulatory Agency (MHRA) has also reviewed and approved this study.

Contact Details

If you have any further questions about the study please contact the research nurse team on

[Insert site contact details]

If you would like to discuss this study with someone independent of the study please contact **Dr Jamie Scott** by email (jamie.cooper2@nhs.scot) or by phone (01224 551817). **[Insert independent contact details]**



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Thank you for taking the time to read this information sheet

CONSENT FORM

Professional Representative (England, Wales & NI)

Participant ID:

Principal Investigator:

Please Initial box

1. I confirm that I have read and understood the Patient Information Sheet – Professional Representative (England, Wales & NI) **v1.4 03 November** ~~v1.3 17 Jun 2022~~ for the above study. I have had the opportunity to consider the information, ask questions and have had these questions answered satisfactorily.
2. I understand that my patient's participation is voluntary and that I am free to withdraw their participation at any time, without giving any reason and without their medical and/or legal rights being affected
3. I give permission for the research team to access my patient's medical records for the purposes of this research study
4. I understand that relevant sections of my patient's medical notes and data collected during the study may be looked at by individuals from the Sponsor (NHS Greater Glasgow & Clyde), from regulatory authorities or from NHS organisations where it is relevant to my patient taking part in this research. I give permission for these individuals to have access to my patient's data and/or medical records
5. I agree to my patient's General Practitioner being informed of their participation in this study
6. I understand that data collected about my patient during the study will be converted to anonymised data
7. I agree to my patient's anonymised data being used in future ethically approved research studies

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NAME OF PERSON GIVING CONSENT	SIGNATURE	DATE
_____	_____	_____
NAME OF INVESTIGATOR/DESIGNEE	SIGNATURE	DATE

When completed: 1 copy for participant; 1 original for researcher site file; 1 copy to be kept in medical notes. A copy will also be uploaded to the eCRF.

CONSENT FORM

Professional Legal Representative Telephone/Witness Consent (England, Wales & NI)

Participant ID:

Principal Investigator:

- I confirm that I have read and understood the Patient Information Sheet – Professional Legal Representative (England, Wales & NI) ~~v1.3-17 Jun-2022~~ **v1.4_03 November** for the above study. I have had the opportunity to consider the information, ask questions and have had these questions answered satisfactorily.
- I understand that my patient’s participation is voluntary and that I am free to withdraw their participation at any time, without giving any reason and without their medical and/or legal rights being affected
- I give permission for the research team to access my patient’s medical records for the purposes of this research study
- I understand that relevant sections of my patient’s medical notes and data collected during the study may be looked at by individuals from the Sponsor (NHS Greater Glasgow & Clyde), from regulatory authorities or from NHS organisations where it is relevant to my patient taking part in this research. I give permission for these individuals to have access to my patient’s data and/or medical records
- I agree to my patient’s General Practitioner being informed of their participation in this study

Please Initial box

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6. I understand that data collected about my patient during the study will be converted to anonymised data
7. I agree to my patient's anonymised data being used in future ethically approved research studies
8. I agree for my patient to take part in the above study

OPTIONAL:

- | | YES | NO |
|---|--------------------------|--------------------------|
| 09. I understand that the samples and data my patient provides can be used to support other ethically approved research in the future, and may be shared anonymously with other researchers | <input type="checkbox"/> | <input type="checkbox"/> |
| 10. I agree to long term follow-up information by record linkage being collected on my patient's future wellbeing and treatment from NHS and Government Health Records (<u>such as NHS digital in England and the electronic Data Research and Innovation Service (eDRIS in Scotland)</u>) | <input type="checkbox"/> | <input type="checkbox"/> |
| 11. I agree for my patient to be contacted about future ethically approved research studies | <input type="checkbox"/> | <input type="checkbox"/> |
| 12. I give permission to give extra samples of my patients' blood for research purposes. I understand how the samples will be collected, that giving the samples is voluntary and that I am free to withdraw my patient's participation at any time without giving a reason and without their medical care or legal rights being affected. | <input type="checkbox"/> | <input type="checkbox"/> |
| 13. I agree to long term storage of my patients' blood for use in future ethically approved research studies | <input type="checkbox"/> | <input type="checkbox"/> |
| 14. I agree for my patient to be contact in the future regarding the genetic analysis of stored blood samples | <input type="checkbox"/> | <input type="checkbox"/> |

Professional Legal Representative Name

Relationship



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NAME OF INVESTIGATOR/DESIGNEE SIGNATURE DATE

Witness Statement

I hereby confirm that the Professional Legal Representative for _____ [PATIENT NAME] _____ has been appropriately informed by as detailed in the patient information sheet.

Witness (PRINT NAME) Date Signature

Designation/relation Date Signature

When completed: 1 copy for participant; 1 original for researcher site file; 1 copy to be kept in medical notes. A copy of the consent form should also be uploaded to the eCRF.