

Participant Information Sheet

Personal Legal Representative (England, Wales & NI)

You are invited to consider giving your permission for your relative to take part in a research study. To help you decide whether or not your relative 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 relative 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 relative 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 relative 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 add in extra salt solution fluid later via a drip if required. Vasopressors work by increasing the blood pressure which allows a better blood flow to the 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 your relative been invited to take part?

Your relative is being considered for taking 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. We are therefore asking you as their nearest relative, welfare attorney or guardian if you will give consent on their behalf to join the study. This is permissible under the Mental Capacity Act 2005.

The Mental Capacity Act 2005 require you to put your own views about the research aside and take into account and consider the present and past wishes and feelings of your relative.

Does my relative 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 relative 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 relative from the study will not affect the healthcare that they receive now or at any stage in the future.

What will happen to your relative if they take part?

A member of the research team will speak to you to discuss your relative'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 your relative's treatment starting. You will then be asked to give written consent. We will review your relative's medical notes including medical history, blood tests, other tests they may have had and any other treatment.

If your relative 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

Your relative 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

Your relative 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 contraception 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 your relative will stop at 48 hours. All other treatment will be decided by the doctor treating your relative, after discussing with you.

Once your relative 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 your relative again to do this.

Taking part in the study should not cause much inconvenience to your relative other than having to answer some additional questions about their health and completing a questionnaire. We will contact

your relative to complete a short questionnaire 30 days and 180 days later. The questionnaire takes less than 5 minutes to complete.

Your relative will not need to come to hospital for any additional visits.

What are the possible benefits of taking part?

There is no guarantee that your relative 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 relatives' infusion site 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 relative will be closely monitored by the healthcare team to monitor any side effects.

Additional Blood Tests

~~Your relative may be asked to give three additional 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. 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 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 relative's 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 your relative and your relative's 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 your relative's information and using it properly. NHS Greater Glasgow & Clyde will keep non-identifiable information about your relative for 20 years after the study has ended.

Your rights to access, change or move your relative'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 your relative from the study, we will keep the information about your relative that we have already obtained. To safeguard your relative's rights, we will use minimally personally identifiable information possible.



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~~Jun 2022~~
Personal Leg Rep (England,
Wales & NI)
IRAS ID: 307862

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

[NHS/other site] will keep your relative's name, [NHS number] and contact details [add other identifiers] confidential and will not pass any of this information other than a copy of your consent form, which confirms that you agreed for your relative 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 your relative about the research study, and make sure relevant information about the study is recorded for your relative's care, and to oversee the quality of the study. Certain individuals from NHS Greater Glasgow & Clyde and/or regulatory authorities may look at your relative'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 your relative and will not be able to find out your relative's name, [NHS number] or contact details.

[NHS/other site] will keep identifiable information about your relative 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 your relative's personal details will be removed. We will record your relative's participation in your relative's medical record so that other doctors involved in your relative'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 relative's future wellbeing by data linkage NHS Greater Glasgow & Clyde will ~~share provide~~ your relative'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 allow them to provide information on your relative's health status. We would also like to let your relative know about other research studies that may be of interest to your relative and will ask your permission to contact your relative 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 relative to be contacted about future research studies your relative'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 your relative's GP of your 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.



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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

In the unlikely event that something goes wrong and your relative 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 relative may have to pay their legal costs.

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

Your relative's 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 relative. You or your relative can contact the study team to find out the final results if you wish.

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 relative will not be identified in any published results.

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



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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

Personal Legal Representative (England, Wales & NI)

Participant ID:

Principal Investigator:

Please Initial box

1. I confirm that I have read and understood the Patient Information Sheet – Personal Legal Representative (England, Wales & NI) ~~V1.4 03 November 2022~~~~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 relative'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 relative's medical records for the purposes of this research study
4. I understand that relevant sections of my relative'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 relative taking part in this research. I give permission for these individuals to have access to my relative's data and/or medical records
5. I agree to my relative's General Practitioner being informed of their participation in this study
6. I understand that data collected about my relative during the study will be converted to anonymised data

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7. I agree to my relative's anonymised data being used in future ethically approved research studies

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8. I agree for my relative to take part in the above study

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OPTIONAL:

YES

NO

09. I understand that the ~~samples and~~ data my relative provides can be used to support other ethically approved research in the future, and may be shared anonymously with other researchers

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10. I agree to long term follow-up information by record linkage being collected on my relative's future wellbeing and treatment from NHS and Government Health Records (such as NHS digital in England and the electronic Data Research and Innovation Service (eDRIS in Scotland))

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11. I agree for my relative to be contacted about future ethically approved research studies

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~~12. I give my permission to give extra samples of my relative's 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 relative's participation at any time without giving a reason and without their medical care or legal rights being affected.~~

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~~13. I agree to the long term storage of my relatives blood for use in future ethically approved research studies~~

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~~14. I agree for my relative to be contacted in the future regarding the genetic analysis of stored blood samples.~~

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I confirm that I am the Personal Legal Representative for [PATIENT NAME]



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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 of the consent form should also be uploaded to the eCRF.

CONSENT FORM

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

Participant ID:

Principal Investigator:

Please Initial box

1. I confirm that I have read and understood the Patient Information Sheet – Personal Legal Representative (England, Wales & NI) ~~V1.4 03 November 2022~~ ~~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 relative'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 relative's medical records for the purposes of this research study
4. I understand that relevant sections of my relative'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 relative taking part in this research. I give permission for these individuals to have access to my relative's data and/or medical records

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5. I agree to my relative's General Practitioner being informed of their participation in this study
6. I understand that data collected about my relative during the study will be converted to anonymised data
7. I agree to my relative's anonymised data being used in future ethically approved studies
8. I agree for my relative to take part in the above study

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OPTIONAL:

YES NO

09. I understand that the ~~samples and~~ data my relative provides can be used to support other ethically approved research in the future, and may be shared anonymously with other researchers
10. I agree to long term follow-up information by record linkage being collected on my relative's future wellbeing and treatment from NHS and Government Health Records (such as NHS digital in England and the electronic Data Research and Innovation Service (eDRIS in Scotland))
11. I agree for my relative to be contacted about future ethically approved research studies
- ~~12. I give permission for my relative to give extra samples of 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 relative's participation at any time without giving a reason and without their medical care or legal rights being affected.~~
- ~~13. I agree to the long term storage of my relative's blood for use in future ethically approved research studies.~~
- ~~14. I agree for my relative to be contacted in the future regarding the genetic analysis of stored blood samples~~

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Personal Legal Representative Name

Relationship



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NAME OF INVESTIGATOR/DESIGNEE

SIGNATURE

DATE

Witness Statement

I hereby confirm that the Personal 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.