**Participant Information Sheet**

**Recovered Capacity (England, Wales & NI)**

You are invited to consider whether you wish to continue taking part in a research study. During your recent admission to hospital you were unable to give consent for entry into the EVIS Trial. We therefore asked your legal representative (welfare attorney, welfare guardian, nearest relative, and independent doctor or an individual appointed by the hospital) who gave consent on your behalf to enter the study. You were entered into the research study by a process approved by the research ethics committee. This is permissible under the Mental Capacity Act 2005. Since you have now recovered the ability to make decisions about your care, we are asking your permission to continue your involvement with the study. Before you decide whether or not to continue, it is important for you to understand why the research is being done and what it will involve. Please take 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 to continue taking part in the trial.

**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 you arrive in hospital. The standard approach is to give a salt solution fluid through a drip in your arm to start with, then later adding in a medication that increases the blood flow to your vital organs (a vasopressor medication called norepinephrine) if required. The alternative approach is to start the vasopressor medication immediately if needed, 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 your 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 was I invited to take part?**

You were admitted to hospital for treatment of infection (sepsis) and your representative agreed that you could join the study. However you are now capable of making an informed decision about whether you wish to continue in the study or not.

**Do I have to continue to take part?**

No, it is up to you to decide whether or not to continue taking part. If you do decide to continue taking part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. Deciding not to take part or withdrawing from the study will not affect the care you receive or any legal rights.

**What will happen to me if I take part?**

A member of the research team will speak to you to discuss your participation in this study and make sure you understand everything. They will explain to you what has already happened to you as part of the study and what we will ask you to do if you choose to continue.

When you were entered into the study you were put at random (like tossing a coin) into one or two treatment groups.

**Treatment 1 – Usual Treatment**

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

**Treatment 2 - Intervention**

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

If you are a woman of childbearing potential, the medicines used in the intervention arm (norepinephrine) may harm an unborn child, this is why the clinical team have performed a pregnancy test prior to going into the study.

**For Treatment 1 and Treatment 2**

Each treatment will be given for as long as they are required, but the trial treatment duration is 48 hours. Collection of data will stop after the 104 day follow-up period is complete. 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 between 31-44 days later and between 91-104 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.

Taking part in the study should not cause much inconvenience to you other than having to answer some additional questions about your health and completing a questionnaire. We will contact you to complete a short questionnaire between 31-44 days later and between 91-104 days later. The questionnaire takes less than 5 minutes to complete.

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

**Is there anything I need to do or avoid?**

No, there is nothing you need to do or avoid if you continue in this study.

**What are the possible benefits of taking part?**

There is no guarantee that you 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 infusion site will be checked regularly by a healthcare professional to minimise any leaking. Another rare side effect of vasopressors is patients may experience an irregular heart rate however you will be closely monitored by the clinical team to monitor any side effects.

**Will my 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 you and your 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 information and using it properly. NHS Greater Glasgow & Clyde will keep information including participant names, sex at birth, CHI/NHS number, and date of birth about you for 10 years after the study has ended. The University of Edinburgh will act as sole data controller for the purposes of data linkage only.

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

The legal basis for your participation in this research is consent. The legal basis for processing your personal data is Article 6(1)(e) of the UK GDPR. Our processing is necessary for the performance of a task carried out in the public interest, and for special category data we rely on UK GDPR Article 9(2)(j) as our processing is for scientific research purposes by way of Schedule 1 Part 1 Paragraph 4 of the Data Protection Act 2018.

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

*[LOCALISE SITE NAME]* will keep your name, *NHS/CHI number* *[delete as appropriate* ]and contact details confidential and will not pass any of this information other than a copy of your consent form, which confirms that you agreed to take part in the study. This will only be looked at by an authorised member of the Study Monitoring team. A member of the Study Monitoring team will look at your uploaded consent on the trial database to ensure the form has been completed appropriately. Data Managers and staff at the University of Edinburgh will have access to the uploaded consent forms in order to perform their administration role and control of the database, however staff viewing your consent will only do so where it is appropriate to their role and they will be fully trained in GDPR and legislation.

*[LOCALISE SITE NAME]* will use this information as needed, to contact you about the research study, and make sure relevant information about the study is recorded for your care, and to oversee the quality of the study. Certain individuals from NHS Greater Glasgow & Clyde and/or regulatory authorities may look at your medical and research records to check the accuracy of the research study.

In addition, a signed copy of your consent form, which identifies you by name will be uploaded to a secure University of Edinburgh server. Where identifiable data is collected or accessed this will be limited to the study monitors wherever possible, but it may become necessary for other members of the trial team from NHS GGC and the University of Edinburgh to access this data under certain exceptional circumstances. All members of the trial team are appropriately trained in the use of data collected from participants and will not access this data without reason.

*[LOCALISE SITE NAME]* will keep identifiable information about you from this study for 10 years after the study has finished.

All data gathered during the study will be coded by a unique identifier meaning that all of your personal details will be removed. We will record your participation in your medical record so that other doctors involved in your 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 future wellbeing by data linkage the University of Edinburgh will share your personal information on behalf of NHSGGC (NHS/CHI number, postcode, date of birth and sex at birth) with NHS departments (such as the electronic data research innovation service (eDRIS (Scotland), NHS England, Sail (Wales)) at the end of the study. This is to allow them to provide us with information of your health status. We would also like to let you know about other research studies that may be of interest to you and will ask your permission to contact you about them. These studies would be subject to funding and regulatory approvals and your consent for this is optional. If you chose to consent to be contacted about future research studies your 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 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.

If you have a concern about any aspect of this study, you should speak to your study doctor who will do their best to answer your 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 you are harmed during the research and this is due to someone’s negligence then you may have grounds for legal action for compensation against *[LOCALISE health board]* but you may have to pay your legal costs.

**What will happen if I don’t want to carry on with the study?**

Your participation is entirely voluntary. You can withdraw from the study at any time without giving a reason, without your medical care or legal rights being affected.

If you withdraw from the study, the information which has been collected about you whilst you have been in the study will 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 you. You can contact your study team if you would like to know the final results.

**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. You 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**

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 Cooper by email (jamie.cooper2@nhs.scot) or by phone (01224 551817).

**Thank you for taking the time to read this information sheet**

**CONSENT FORM**

**Recovered Capacity (England, Wales & NI)**

Participant ID:

Principal Investigator:

Please Initial box

|  |  |  |
| --- | --- | --- |
| 1. | I confirm that I have read and understood the Patient Information Sheet – Recovered Capacity (England, Wales & NI) **V4.0 09 December 2024** 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 participation is voluntary and that I am free to withdraw at any time, without giving any reason and without my medical and/or legal rights being affected. |  |
| 3. | I give permission for the research team to access my medical records for the purposes of this research study. |  |
| 4. | I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from the Sponsor (NHS Greater Glasgow & Clyde), from regulatory authorities, the University of Edinburgh or from NHS organisations where it is relevant to my taking part in this research. I give permission for these individuals to have access to my data and/or medical records. |  |
| 5. | I agree to my General Practitioner being informed of my participation in this study. |  |
| 6. | I understand that data collected about me during the study will be converted to anonymised data. |  |
| 7. |  I give my permission for a signed copy of my consent form to be uploaded to the University of Edinburgh server, where the study monitors and other members of the trial team from NHS GGC and the University of Edinburgh have access |  |
| 8. | I agree to take part in the above study.  |  |
|  |  |  |
| **OPTIONAL:** | **YES** | **NO** |
| 09. | I understand that the data I provide 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 future wellbeing and treatment from NHS and Government Health Records (such as eDRIS (Scotland), NHS England, Sail (Wales)  |  |
| 11. | I agree to be contacted about future ethically approved research studies. |  |

NAME OF PARTICIPANT SIGNATURE DATE

NAME OF INVESTIGATOR/DESIGNEE SIGNATURE DATE

***Witness statement – (***for those mentally capable but physically unable to sign consent)

I hereby confirm that \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_was fully informed of the study as detailed in

Name of patient (PRINT NAME)

this information sheet and that informed consent was freely given.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
|  |  |  |  |  |
| Witness (PRINT NAME) |  | Date |  | Signature |
|  |  |  |  |  |

|  |  |  |
| --- | --- | --- |
| Designation/ relation |  |  |

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