Portsmouth Hospitals NHS Trust

Critical Care Department
Queen Alexandra Hospital
Cosham
Portsmouth PO6 3LY
Tel: 02392 283653

Detecting Heart Failure in Septic Shock (GLASSheart)

We'd like to invite you to take part in our research study

Before you decide, it is important that you understand why the research is being done and what it would involve for you. Please take time to read this information, and discuss it with others if you wish. If there is anything that is not clear, or if you would like more information, please ask us.

Important things you need to know

- We want to find ways to better and quicker identify any heart failure in patients who have sepsis or septic shock using cardiac ultrasound and blood samples
- We want to follow up people taking part for one year to see if we can identify any long term effects of septic shock.
- There are no additional medications or changes to your treatment while taking part

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If you have any questions please contacting of the investigating team: Emma Lane (chief cardiac physiologist), Richard Clinton, Jonarthan Thevabayagam or Dave Slessor (intensive care consultants)via GLASSheart@porthosp.nhs.uk

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- You can stop taking part at any time. This will not affect the care you receive.

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What is the purpose of the study?

This study aims investigate if ~~to use~~ new ultrasound techniques ~~not standardly used, and~~together with blood samples may help to detect heart failure sooner than current methods in patients who are on the Intensive Care Unit with sepsis or septic shock~~.~~. We also want to follow up these patients with further ~~(additional to standard care)~~ ultrasound scans and blood tests after they have recovered to see if we can find out more information on what happens to heart function after leaving hospital. This has not been investigated before. For follow up visit after discharge, travel expenses will be covered by means of a taxi (up to £20 total per visit).
These scans and blood samples are additional to standard care and for research purposes. ~~This has not been investigated before~~

Why have I been invited?

You have been invited to take part in this study because you have been admitted to Intensive Care with sepsis or septic shock. We plan to recruit 108 participants from Queen Alexandra Hospital Intensive Care Unit.

Do I have to take part?

Participation in our study is entirely voluntary. If you decide to take part, you will be asked to sign a consent form. If you do not wish to take part, you will not have to give a reason and your decision will not affect the care you will receive. Similarly, if you do decide to take part, you will be able to withdraw from the study at any time and without giving a reason, and without any effect on the medical care that you receive.

How will my GP know I am participating?

With your consent, we will inform your General Practitioner of your participation in this study.

Can I decide not to carry on with the study?

If you decide to take part in the study but then change your mind, you will be free to withdraw at any time without giving a reason (although we will appreciate it if you tell us why you change your mind). Your care will not be affected in any way. If you

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withdraw from the study, we will destroy all your identifiable blood samples, but will use all data collected up to your withdrawal (see section on 'how your information is used')

What are the possible risks to taking part?

This research does not involve any invasive procedures or ionising radiation (X-rays). The ultrasound scan is a quick and painless procedure (around 20-30mins), although the gel can feel a little cold! It is not impossible, but rare to have an allergic reaction to the ultrasound gel or sticky ECG electrodes. The blood test carries the same risk as any other standard blood test, whereby there can be discomfort or bruising at the sample site.

What are the possible benefits to taking part?

Whilst there are no immediate benefits for those people participating in the study, it is hoped that your involvement will allow us to better understand the impact of septic shock. This may be influential in shaping how staff treat and identify people with sepsis and septic shock in the future.

Will taking part affect my treatment?

Your stay in Intensive Care will not change in any way and you will still receive the same tests, treatment and standard of care as anyone not on the study.
-The scans and blood samples are additional to standard care and for research purposes.

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Where can you find out more about how your information is used?

Portsmouth Hospitals NHS Trust is the sponsor for the study based in the United Kingdom. We will be using information from you and your medical records in order to undertake this study and will act as data controller for this study. This means that we are responsible for looking after your information and using it properly. Portsmouth Hospitals NHS Trust will keep identifiable information about you until the study visit is complete.

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Your right to access, change or move your information is 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 the minimum personally identifiable information possible. You can find out more about how we use your information: https://www.porthosp.nhs.uk/departments/Research/research-innovation.htm

We will collect information from you and your medical records for this research study. Individuals from Portsmouth Hospitals NHS Trust and regulatory organisations may look at your medical and research records to check the accuracy of the research study. The only people in Portsmouth Hospitals NHS Trust who will have access to information that identifies you will be people who need to contact you to regarding your participation in the study or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details.

You will be allocated a unique study number and all your data will be collected against this number therefore no information such as your name or date of birth is used. The data collected will be locked in the research department. The digital data will be stored on a password protected computer on a secure NHS server.

Who has reviewed this project?

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee to protect the safety rights, wellbeing and dignity of patients. This study has been reviewed and approved by a Research Ethics Committee. A group of Patient Research Ambassadors have also reviewed this project.

Who is organising the research?

This research has been sponsored by is Portsmouth Hospitals NHS Trust and supported by the National Institute of Health Research. The project is part fulfilment of a PhD with University of Portsmouth, and is lead by Emma Lane Chief Cardiac Physiologist. Portsmouth Hospital consultants from Intensive Care and Cardiology are also part of the team involved in this project.

What if there is a problem?

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If you have a concern about any aspect of this study or your wider care then we would encourage you to ask to speak to one of the investigating team who will do their best to resolve any issues you may have. If you remain unhappy and wish to make a formal complaint, you can do this by contacting the hospital's Patient Advice and Liaison Service (PALS). PALS can be contacted by phone on 02392 286757 or email (PALS@porthosp.nhs.uk). The PALS service can also be used to ask for more advice about taking part in research.

What will happen to the results of the study?

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When the results of the study are known, we will publish the overall findings of the study in medical journal(s) and national conferences for consideration by the National Institute for Health and Care Excellence (NICE). Information that identifies you personally will not be presented.

Public sharing of study results will be done locally by group meetings and presentations, if you wish to be informed of these events please let one of the researchers know. Alternatively if you wish to be informed of the final study results by post please indicate this by providing your address or email when signing the study consent form. Results may take up to 4 years from date of consent.

Contacts for further information (8am -5pm only)
Chief Investigator: Emma Lane – Cardiac Physiologist. Tel 02392 286000 x 5337

Critical Care Research Team: Tel 02392 286000 ext 6035

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What is involved?

Stage 1 (within 24hrs of consent)

Collecting baseline information and medical history
Echocardiogram (ultrasound) of your heart
Two Blood tests &
Urine Dip Test
Electrocardiogram (ECG)

Stage 2 (72hrs later)

Echocardiogram (ultrasound) of your heart

Stage 3 (23-37 days after stage 1)

Echocardiogram (ultrasound) of your heart
Two Blood tests &
Urine Test

Stage 4 (83-97 days after stage 1)

Echocardiogram (ultrasound) of your heart
Two Blood tests &
Urine Dip Test

Stage 5 (11-13 months after stage 1)

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Write a section of what their participation will involve.
-Who will be doing the tests
-Where will it be done
-What data is collected

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Follow up phone call (about 5-10mintes) to discuss any changes to medical health since stage 4.