INVESTIGATOR SITE HEADED PAPER

Sepsis Trials in Critical Care - SepTiC
Patient Information Summary and Consent form

We are inviting adults who have been admitted to the Intensive Care Unit (ICU) with sepsis to participate in our research study. Sepsis is when the body overreacts to an infection and starts to damage itself. This study is trying to find the best treatments for sepsis. This form provides summary information on the study, the treatments we are using, and risks and benefits of taking part.

Please take time to read the following information carefully and do talk about it with other people if you would like to. Ask us if there is anything that you do not understand or if you would like more information. You can take time to think about your participation.

What are the treatments?

We are testing three different treatments in this study: -

1. Diagnostic Trial – this involves a PCR test that quickly tells us what bacteria may be causing the infection and may help us decide which antibiotics to give.
2. Fluid Trial – giving fluid is routine when treating sepsis, but there is no clear guide on how best to provide the treatment, so we will test how much fluid should be given and if medication should be given to remove any build-up of extra fluid.
3. GM-CSF Trial – this drug can help the immune system fight infection by making more white blood cells.

These treatment options listed above also include a 'standard care' or 'placebo' option. A computer randomly selects which treatment options you will receive. This means you may not receive any of these treatments, even if you choose to participate in the SepTiC trial. How patients recover over time is then compared between the different treatment options to work out which treatments are best.

Which treatments will I receive and what do I need to do?

Your doctor will decide whether you are suitable to participate in all or part of this trial. A few extra blood tests may be taken (a couple of tablespoons) while you are in intensive care, usually from 'drips' already in place.

You do not need to do anything for the study while you are in hospital. We will collect data from your hospital records and other NHS linked data. We may contact you 3 months later to see how you are and would like to contact you at 6 months with a short telephone call to ask about your quality of life, and wellbeing.

So that we can treat patients as quickly as possible some of these treatments may already have started, you do have the option to stop these if you prefer to do so.

Participation into the SepTiC trial is voluntary. All patients, including those that do not wish to participate in SepTiC, will receive the best standard of care available at this hospital.

More detailed information about the study including how we use patient data and privacy, legalities and insurance of the study, risks and benefits, how to make a complaint and how to find out the results of the study can be found in our full patient information sheet. (A written copy is available or is available online at www.septictrial.co.uk)

If you are happy to proceed, please complete the attached consent form.

Site Contact Information
Investigator name:-
Site Contact details:-

Study Contact Information
Please contact The **SepTiC** Trial team using the following contact details:
Name: The **SepTiC** Trial Team
24hr Telephone: 0207 5949725
Email: septic@imperial.ac.uk
Website: www.septictrial.co.uk

Thank you very much for taking part in this study!

A copy of the written information and signed Informed Consent form will be given to you to keep.

Consent Form for Participants

Full Title of Project: Sepsis Trials in Critical Care - SepTiC

Site number:	
Patient Number:	
Patient Name:	
Name of Principal Investigator:	

Please initial box

1. I confirm that I have read and understand this document and have read/received a copy of the appropriate patient information sheet and privacy notice for **SepTiC.**	
2. I confirm I am happy to consent to continue to participate in the following trials: Diagnostic and Fluid Trial ☐ GM-CSF Trial. ☐	
3. I confirm that I understand the **SepTiC** study and I have had the opportunity to ask questions which have been answered fully.	
4. I understand that my participation is voluntary, and I am free to withdraw at any time, without giving any reason and without my legal rights nor treatment / healthcare being affected.	
5. I understand that sections of any of my medical notes may be looked at by responsible individuals from Imperial College London, from the NHS Trust or from regulatory authorities where it is relevant to my taking part in this research.	

6. I give consent for information collected about me to be used to support other research or in the development of a new test, medication, or treatment by an academic institution or commercial company in the future, including those outside of the United Kingdom (which Imperial has ensured will keep this information secure).	
7. I give consent for samples (human tissue) collected about me to be used to support other research or in the development of a new test, medication, or treatment by an academic institution or commercial company in the future, including those outside of the United Kingdom (which Imperial has ensured will keep this information secure).	
8. I understand that tissue samples and / or data collected from me are a gift donated to Imperial College and that I will not personally benefit financially if this research leads to an invention and/or the successful development of a new test, medication treatment, product or service.	
9. I give consent to being contacted about the possibility to take part in other research studies.	
10. I consent to allow the use of data already collected in the trial, as well as ongoing data collection and follow up information to be obtained from my medical records at 3, 6 months and 12 months after my inclusion	
11. I agree that my medical records and other personal data generated during the study may be examined by representatives of the sponsor (Imperial College London), by people working on behalf of the sponsor, and by representatives of Regulatory authorities, ICNARC, NHS Digital and SICSAG where it is relevant to my taking part in this research.	
12. I agree to my tissue samples being used to undertake genetic research which may have the potential to generate data that can be tracked back to me	
13. I consent to take part in **SepTiC**	

_____	_____	_____
Name of patient	Signature	Date
_____	_____	_____
Name of staff member *(Listed on delegation log)*	Signature	Date

1 copy for participant; 1 copy for Principal Investigator 1 copy for hospital notes

To ensure confidence in the process and minimise risk of loss, all consent forms must be printed, presented, and stored in double sided format