INVESTIGATOR SITE HEADED PAPER

Sepsis Trials in Critical Care - SepTiC

Professional Legal Representative - Information Summary

What is it?

SepTiC is a clinical trial designed to investigate treatments for sepsis. There are different treatments available in this trial, these are described below.

You are being asked to provide your independent professional opinion and consent for a patient who does not have capacity to do so. We would like to know if, in your opinion the patient has no objection to participating in this study and you see no reason why they should not be included in this study. As the patient does not have capacity to provide informed consent and a relative, friend, partner may not be available to provide their consent, we seek your professional opinion. Should the patient regain capacity, we will always seek their informed consent to ensure they are happy to continue to participate in the study after inclusion.

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 is causing the infection and may help us decide which antibiotics to give.
2. Fluid Trial – giving fluid is routine practice in 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 diuretics 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. The patient will be randomised to these treatments, which, depending on the outcome, may result in the patient not receiving any of these treatments. We will then compare how patients recover over time between the different treatment options to work out which treatments are best.

Will all treatments be offered?

All routine treatments that are available at this hospital will be offered.

What does the patient need to do?

The patient does not need to do anything for the study while they are in hospital. We will collect data from their hospital records and other NHS linked data. We may contact them 3 months later to see how they are and would like to contact them 6 months later with a short telephone call to ask about their quality of life, and wellbeing. A few extra blood tests may be taken (20-40mls) while they are in intensive care Participation in 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 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 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.

Consent Form for Participants Unable to Give Consent Themselves

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 give consent for this patient 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 I am giving this consent based on what I believe would be the person for whom I am providing consent's wishes. In my opinion they would be willing to participate.	
5. I understand that their participation is voluntary, and I or the person I am consenting for are free to withdraw at any time, without giving any reason and without any legal rights nor treatment / healthcare being affected.	
6. I understand that sections of any of the patient's medical notes may be looked at by responsible individuals from Imperial College London, from NHS or from regulatory authorities where it is relevant to my taking part in this research.	
7. I give consent for information collected about the person for whom I am giving consent 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 give consent for samples (human tissue) collected about the person for whom I am giving consent 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).	

9. I understand that tissue samples and / or data collected are a gift donated to Imperial College and that I or the person I am consenting for will not personally benefit financially if this research leads to an invention and/or the successful development of a new test, medication, or treatment.	
10. I give consent for the patient to being contacted about the possibility to take part in other research studies.	
11. I agree that the person for whom I am giving consent will override my consent on their behalf if or when they are able to give informed consent themselves.	
12. I consent to allow the use of data already collected by the patient in the trial, as well as ongoing data collection and follow up information to be obtained from the patient's medical records at 3, 6 months and 12 months after their inclusion.	
13. I agree that the medical records for the person for whom I am giving consent 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 their taking part in this research.	
14. I agree to the patient's tissue samples being used to undertake genetic research which may have the potential to generate data that can be tracked back to them.	
15. I agree to the person for whom I am giving consent taking part in the **SepTiC** study.	

_____	_____	_____
Name of Professional Legal Representative (*not listed on study delegation log*)	Signature	Date

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

1 copy for participant; 1 copy for Principal Investigator 1 copy to be kept with 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