Innate-like T cells in sepsis (ILTIS): Implications for early diagnosis and rescue of immune suppression – a feasibility study

CONSULTEE INFORMATION SHEET
Version 1.5

Why have I been given this leaflet?
You have been given this leaflet because your friend/relative has been admitted to the Intensive Care Unit (ICU) suffering from a severe infection called sepsis.

We are working with people with severe infections, which we hope will lead eventually to the development of new treatments and tests. We would like your help with this work.

Before you decide whether or not to work with us, we would like you to understand why the work is being done and what it involves. One of our team will go through this leaflet with you and answer any questions you may have

What is the purpose of the study?
Sepsis is a potentially life-threatening condition caused by a severe infection. When someone develops sepsis, inflammation occurs not just at the site of the infection but throughout the whole body. This widespread inflammation can be very harmful.

We are asking for consent to take samples from some patients with sepsis in the hope to study the way the body responds to severe infections. This includes patients that test positive for COVID-19.

We will be looking in detail at white blood cells that help to co-ordinate the reaction to infection. We also examine the specialised hormones in the blood (called cytokines) to see if they can be used to predict what kind of infection is present. We will also be adding drugs to your immune cells after being taken out of the body to see if we can improve their response to infection. This may lead to new treatments.

Do I have to agree to take part?
It is up to you to decide on behalf of your friend/relative whether or not to take part. We will describe the study and go through this leaflet with you. If you agree for your friend/relative to take part, we will then ask you to sign a consent form. However, you are free to withdraw them at any time, without giving a reason. Saying yes or no will not affect their standard of care.

What does the study involve?

Whilst your friend/relative is on the Intensive Care Unit, many blood tests will be taken as part of their routine care. We want to take some extra blood from him/her in order to see what effect the inflammatory reaction is having on their white blood cells

We want to take **90 ml** (about nine tablespoonfuls) of extra blood on top of the two pints or more that are usually taken during the course of a stay on the intensive care unit. The blood samples are taken out of one of the tubes that your friend/relative already had put in as part of their care – there are no extra needles. The extra blood will be taken over the course of a week.

We will also take two samples of mucus by adding and then suctioning out 20 ml of a mild salt solution from the air passages in the lungs using a plastic tube already in your friend/relative's mouth. Taking these sample will occur when the patient is sedated, and so any discomfort will be very mild and transient if any at all.

As part of this study we may carry out an analysis of your friend's/relative's DNA. The types of analysis we will perform are for research purposes only and therefore we will not be able to provide any clinical feedback.

The Cardiff University research team will also need access to your friend's/relative's medical records to learn how his/her condition and the treatment they are receiving may affect the inflammatory reaction in their body.

The data obtained in this study are important and may be useful to other research studies. So that your friend's/relative's data can be used anonymously for further research in the public interest, an NHS organisation will replace their identifying details with a unique anonymous code. This will enable their data to be linked to routinely collected data, including their health records, both now and in the future. The data can then be used for research in anonymous form in a secure environment.

Will it benefit my friend/relative to take part in the study?

Your friend/relative will receive the same care as they would have if they were not taking part in the study. We hope that taking part will help us to treat other people who may become ill with severe infections, but there will be no direct benefit to your friend/relative as a result of having taken part. We are not able to make any payments to people.

Will he/she be harmed as a result of taking part in this work?

We do not believe that your friend/relative will come to any harm as a result of the study. It is not possible that the extra blood taken could cause any harm because the amount of blood taken is too small. The average adult has about 5 litres (nearly 10 pints) of blood; the amount involved in our samples is a total of **90** ml (or about **nine** tablespoonfuls) over the course of two weeks, which is a tiny extra amount.

What if there is a problem?

If you or your friend/relative have any complaints or concerns about the way they have been treated as a result of taking part in the work, these will be addressed in full. More details are given below.

Will his/her personal details be protected?
Yes. All information will be handled in confidence. All information that is collected about your friend/relative during the course of the research will be kept strictly confidential, and any information about him/her that leaves the hospital will have their name and address removed so that it cannot be identified back to them.

What if my friend/relative decide to leave?
Patients will be fully informed about the study and retrospective consent will be sought upon regaining capacity. Your friend/relative is able to leave the study at any time without having to explain their decision. If this happens we will destroy any samples we have already taken, delete any data stored on computer and shred any of their paper records about the study. He/she will continue to receive the same high standard of care as they would have received in any case.

What if my friend/relative have a complaint about the conduct of the study?
If your friend/relative is in any way unhappy about how the study has been carried out, he/she can discuss this with any member of the team, whose names and contact numbers are listed below. If this does not resolve the issue to their satisfaction, we ask them to take up matters with the Cardiff and the Vale NHS Trust (contact details are also given below). Remember, he/she can always raise any concerns with any of the doctors or nurses who are looking after them.

What will happen to the blood and mucus samples?
The samples will be stored anonymously in secure freezers at Cardiff University until they can be analysed for the chemicals we are interested in. Only members of the Cardiff University research team will have access to the samples. The samples may be shared with other academic or commercial research teams in the UK or overseas. No patient identifiable information will be shared with the collaborating institutions. Any samples that have not been used within five years of the end of the study will be destroyed.

What will happen to the results of the study?
The results of the study will be published in the scientific press and presented at conferences and at other scientific meetings. No individual participants will be identified in any published material. We will also produce a report summarising our findings which will be made available to participants or their relatives. Please let a member of the research team know if you would like to receive a copy. We may also use the anonymised results in future research studies. Your anonymous research data will be retained for 15 years after the study has finished, in line with Cardiff University's record retention policy.

Who is organising and funding the research?
The research is being funded by The European Commission Horizon 2020 fund and organised jointly between Cardiff University and Cardiff and the Vale NHS Trust.

Summary

What is involved?

- We will take 90 ml of blood from lines that are already in.
- We may also take two samples of mucus from the plastic tube already in their mouth.
- No extra needles will be used.
- These samples will be examined for immune cells and experiments done on it to develop new treatments and tests for patients in the future.
- We will also use relevant information from their medical record.
- Identifying details will be replaced with a unique anonymous code to enable their data to be linked to routinely collected data, including their health records, both now and in the future
- All information and samples will be kept strictly confidential.

What are the possible benefits of taking part?

- Participating in this research will not change the participant's treatment in any way.
- Although it will not directly benefit them, it may help other patients in the future going though similar surgery.
- There are no financial benefits to taking part.

What are the possible disadvantages and risks of taking part?

- There are no specific risks.
- The average adult has about 5 litres (nearly 10 pints) of blood; the amount involved in our samples is a total of **90 ml** (or about **nine** tablespoonfuls) over the course of two weeks, which is tiny by comparison.

Further supporting information

What if something goes wrong?
For complaints or problems please contact Dr Matt Wise on 02920 747747 or mattwise@doctors.org.uk. He is the research lead for critical care who is external to the study team but who is familiar with the study.

What if there are serious medical findings from the genetic tests?
Only specific immune cells associated with infection will be assessed. We will not be able to make conclusions about broader aspects of health from these. There will be no implication for other members of your family.

How have patients and the public been involved in this study?
We have discussed this project with the patient and public representative and executive director of the UK Sepsis Trust for Wales. They have made a valuable contribution to how the study is designed and run.

Who has reviewed this study?
Both Cardiff University and the University Hospital of Wales have reviewed this study. It has been granted ethical approval by the Wales Research Ethics Committee 3.

Further information and contact details
For further details please contact Dr Matt PG Morgan on morganMP@cardiff.ac.uk or 029 20744193.

Thank you for taking the time to read this information leaflet.

For further information or complaints please contact:

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