Participant information sheet

Study title: MODET, Multiple Organ Dysfunction in Elderly Trauma.

IRAS: 209230

We would like to invite you to take part in a research study. Before you make a decision, you need to understand why the research is being done and what it would involve, so please take time to read the following information carefully. We will visit you again in a day or two to see if you have any questions about the study. We encourage you to discuss this with a family member or a friend if you are unsure.

The name of the study is: **MODET, Multiple Organ Dysfunction in Elderly Trauma.** The title of the study means it is research that will be carried out with patients who are admitted to hospital following an injury (trauma) and may have developed a complication known as organ dysfunction.

What is the purpose of this study?

Trauma or injury can cause both physical and psychological problems for patients. After admission to hospital the injured patient may be physically unwell for a time and need to be cared for in a critical care unit. Some patients may develop organ dysfunction after their injury. **The definition of organ dysfunction is where one or more organs (such as the liver or lungs) are temporarily not working as they did before the injury**. The affected organs will require medical intervention, such as oxygen or medications until they recover over a period of days or weeks. It appears that older people suffer more of these problems, therefore we would like to investigate what might contribute to this in elderly trauma patients (aged 65 or more) in comparison to younger people (less than 65 years of age).

The aim of this study is to understand how many trauma patients develop organ dysfunction, how severe it is and at what stage it occurs after their injury. We would also like to gain feedback from trauma patients on their experience of their recovery in the months after discharge from hospital to help us understand the longer term effects of organ dysfunction. We will compare the experiences of older and younger trauma patients.

Why am I being invited to participate?

You are currently in hospital after an injury. The critical care staff monitor your progress every day and by analysing things such as your oxygen levels and blood test results they can see how your organs are functioning. They will record if you have developed organ dysfunction, when it started and how long it lasted. This information will be anonymised so that none of your personal details such as your name, age or address are recorded in the research sheet.

We are asking you to provide consent to allow us to continue to collect this anonymised information about your time in hospital. We also ask you consent to allow us to contact you at 12 months after discharge from hospital to see how your recovery is progressing. To find out where you are at this time point, we will need to contact your General Practitioner (GP) or the check the central NHS register at 10 months after injury and therefore ask for your consent to do this.

There are no extra medications used or extra blood tests taken as a result of being in this study.

Do I have to participate?

No, you can choose whether or not to participate, there is no obligation to take part in this study. If you decide to participate you will be given this information sheet to keep and you will be asked to sign a consent form. You are still free to change your mind at any time during the study without giving a reason. If you decide not to participate in the study you will receive the same medical care. Your legal rights will not be affected.

What does participation involve?
Approximately one year after you are discharged home we would like to contact you via telephone, post or email, to complete a short questionnaire (whichever you would prefer). This will take approximately 15 minutes to complete.

What if I change my mind?
You can withdraw your consent to be in the study at anytime. If you decide to participate, you are still free to change you mind at any time without giving a reason. A decision not to continue or to withdraw will not affect your care in any way and you will not be contacted for follow up. The anonymised information we have collected to date will be included in the research.

What are the benefits of participating?
Whilst there are no immediate benefits for those people participating in the project, it is hoped that the results will assist us in understanding the experience of organ dysfunction and improve the recovery of future trauma patients.

What risks to me are there through participating?
There are no risks to you through participating in this research. All data that we collect will be completely anonymised.

Who will know that I am in the study?
Your clinical team, the person who asked your permission to be in the study (consent) and the person who contacts you a year after injury will know.

Will my taking part in this study be kept confidential?
Yes. All information obtained during the course of this study will be kept confidential. You will be identified using a unique study number rather than using any personal information. The anonymised data will be kept for 20 years after the end of the study and stored in secure storage.

What will happen to the results of the research study?
Once the study is completed the results may be published in Scientific and Medical Journals and presented at health professional meetings. You will not be identifiable in any publications or presentations resulting from this study.

Will I ever be contacted again in the future about this?
No you will not be contacted in the future with regards to this study. However, you can track progress of the study and other trauma studies on our website: http://www.c4ts.qmul.ac.uk/

Who has reviewed this study?
This study has been given a favourable ethical opinion by the London South East Research Ethics Committee on 26th October 2016.

What if something goes wrong?
Queen Mary University of London has agreed that if you are harmed as a result of your participation in the study, you will be compensated, provided that, on the balance of probabilities, an injury was caused as a direct result of the intervention or procedures you received during the course of the study. These special compensation arrangements apply where an injury is caused to you that would not have occurred if you were not in the trial. These arrangements do not affect your right to pursue a claim through legal action.

Queen Mary University of London is the sponsor for this study based in the United Kingdom. We will be using information from 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. Queen Mary University of London will keep identifiable information about you for 20 years after the study has finished.

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 the minimum personally-identifiable information possible.

You can find out more about how we use your information at http://www.jrmo.org.uk/

If you have any questions about the study please contact the chief investigator Dr Elaine Cole at Queen Mary University London on 020 359 40731 or via email: e.cole@qmul.ac.uk

Thank you for taking the time to consider participation in the study.