Cardiac Injury and Anaemia Following Surgery for Fractured Neck of Femur: An Observational Study

We would like to invite you to take part in a research study. Before you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish. Contact us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?
We are investigating the incidence of complications after surgery for a broken hip (fractured neck of femur). Patients undergoing surgery for this condition are at risk of complications including heart or kidney damage. We are particularly interested in the incidence of these complications and whether they are affected by having blood transfusion. We hope the information from this study will help us plan a future trial looking at the best level to give blood transfusion in with a broken hip (fractured neck of femur).

Why have I been asked to take part?
You have been asked to take part as you have been admitted to hospital with a broken hip (fractured neck of femur).

Do I have to take part?
No, it is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time and without giving a reason. Deciding not to take part or withdrawing from the study will not affect the healthcare that you receive, or your legal rights.

What will happen if I take part?
You will receive usual standard care. In addition, we will test your blood and urine for very sensitive tests of heart attacks and kidney damage. Where possible we will use the blood tests that you have as part of your routine care, so you will not additional any further blood tests. This blood test, called a “troponin test”, usually takes about a teaspoon of blood (5mls) and is taken before surgery and on the first and third day after surgery. The results of this test will be used as part of the research and will not be available to the doctors looking after you. This is because at the moment we are not sure of its significance in the setting of broken hip. In addition, we will also collect 2 urine sample from you after your operation. We will not store any blood samples for future use but we will store your urine samples. We will take a “fingerprick” blood test to measure your blood count immediately after surgery and will also perform a heart tracing, (also known as an electrocardiogram) on the third day after your operation. We will use information collected in your medical notes during your hospital stay and for up to six months. All data for the study will be identified by the anonymous codes rather than your name. After three months we will either visit or telephone you to undertake a short 5-minute survey on quality of life. If you become unable to consent

during the course of your hospital stay, we will keep you enrolled in this study. Your GP will be informed that you are taking part in this study.

What are the possible benefits of taking part?
There are no direct benefits to you in taking part in this study, but the results from this study might benefit other patients who need surgery for broken hip (fractured neck of femur).

What are the possible disadvantages and risks of taking part?
We are not aware of any risks of taking part in this study.

Will my taking part in the study be kept confidential?
All the information we collect during the course of the research will be kept confidential and there are strict laws that safeguard your privacy at every stage.
Study researchers will need access to your medical records and data to carry out this research. Identifiers (such as name, address, date of birth) will be removed from all data. We will inform your GP of your participation in this study.

How do I take part?
If you are interested in taking part in this study, a member of the research team will come and talk to you within the next 24 hours in order to answer any questions that you may have, and take your consent to take part.

What will happen to the results of the study?
The study will be written up and published in Scientific and Medical journals, and presented at meetings of health professionals. You will not be identifiable in any published results. It may take one to three years after the study is entirely completed for results to be published. You can request a copy of the published results from the Site Principal Investigator.

Will I ever be contacted again in the future about this?
You will be contacted approximately 90 days (3 months from now) to undertake a short quality of life questionnaire. This will take 5 minutes.

Who has reviewed the study?
This study has been given a favourable ethical opinion for conduct in the NHS by a research ethics committee (Scotland A Research Ethics Committee). NHS management approval has also been obtained.

If you have any further questions about the study please contact the Principal Investigator:

Dr Michael Gillies, Consultant in Intensive Care Medicine.
Royal Infirmary of Edinburgh
Little France Crescent
Edinburgh
EH16 4SA
Telephone: 0131 242 3193
or email: Michael.Gillies@nhslothian.scot.nhs.uk

If you would like to discuss this study with someone independent of the study please contact:

Dr Neil Young
Consultant in Intensive Care and Anaesthesia
Royal Infirmary of Edinburgh
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Edinburgh
EH16 4SA
Tel: 0131 242 1186
Email: Neil.Young@nhslothian.scot.nhs.uk

If you wish to make a complaint about the study, please contact NHS Lothian:

Patient Experience Team,
NHS Lothian
2nd Floor
Waverley Gate
2-4 Waterloo Place
Edinburgh
EH1 3EG
Tel: 0131 536 3370

Email: feedback@nhslothian.scot.nhs.uk

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