JUN 16, 2023

OPEN ACCESS

DOI:
dx.doi.org/10.17504/protocols.io.4r3l27k84g1y/v1

Document Citation: Christopher Hawthorne, Keenan Smith, Malcolm Watson, Martin Shaw, Jonathan Cavanagh, Eric Jackson, Shona McKay, Matthew Sheridan 2023. Patient Information Sheet 1.2. **protocols.io** https://dx.doi.org/10.17504/protocols.io.4r3l27k84g1y/v1

Created: Apr 18, 2023

Last Modified: Jun 16, 2023

DOCUMENT integer ID: 80691

R+D Reference: GN21OR387

IRAS Reference

Patient Information Sheet 1.2

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ABSTRACT

Patient information sheet for Predicting Cognitive Decline After Spinal Surgery (PROTECT).

PATIENT INFORMATION SHEET

1.Study Title
PROTECT-PRedicting c**O**gni**T**ive d**EC**line af**T**er spinal surgery

2.Introduction
Before you decide whether to take part in this research it is important for you to fully understand why the research is being done and what it will involve. Please take your time to read the following information carefully. Ask your study doctor or nurse if there is anything that is not clear or if you would like more information.

3.What is the purpose of the Study?
The purpose of the study is to understand why patients sometimes get confused following a surgical operation under a general anaesthetic.

4.Why were you invited to take part?
You have been asked to take part as because you have been scheduled for spinal surgery and you will require a general anaesthetic for this procedure.

5.Do you have to continue to take part?
Your participation in the study is voluntary. It is up to you to decide whether to take part or not. If you decide to take part, you will be given this Patient Information Sheet to keep and be asked to sign a Patient Informed Consent Form. You are free to change your mind or withdraw from the study at anytime and without giving reason. Your decision will not affect in any way the standard of care you receive. If you decide to withdraw from the study blood samples and data collected up until that point may still be analysed.

During the study there is a possibility that you will become confused because of the effects of your surgery and anaesthetic. Providing that study procedures are not felt to be causing you any distress, we will continue to include you in the study. If this is the case we will consult with your Welfare Power of Attorney (if one has been appointed) or your nearest relative/ accompanying adult.

6.What has happened to you so far and what will happen if you continue to participate?
The doctor or nurse looking after you will take a 10 mls (2 teaspoons) sample of blood before your operation and a further 10 mls (2 teaspoons) blood sample the day after your operation. Where possible this will be taken at the same time as other routine blood samples. The sample will be analysed to look at biochemical markers of inflammation which may be associated with confusion after a surgical operation under a general anaesthetic.

During your operation your brain activity will be monitored by sticky skin electrodes which detect the electrical activity of your brain when you are anesthetised during your spinal surgery.

We will also ask you to take some mental tests that will determine memory and other brain function before the operation, in the five days after the operation and at six months after the operation.

The anonymised data and excess samples will be stored at the Institute of Infection, Immunity and Inflammation Research Tissue Bank (I3I RTB), University of Glasgow, for approved medical research. Your samples will only ever be used in research applications which have been approved by a review committee, which will make sure that the

researchers who want to use your samples are properly qualified and that the studies they suggest are sensible. It is hoped your tissue would support a wide range of research studies which will allow us to better understand inflammation, inflammatory diseases, infection, and other related conditions.

Your tissue may be used to create cell lines, where your cells could be grown and cared for in a laboratory for multiple experiments possibly over months and years. Your tissue will not be used in reproductive cloning or for non-medical and non-scientific purposes. Researchers within the NHS, at universities, research institutions or in commercial companies may have access to your samples and data. Any samples and data given to researchers will have had your name, address, and any other personal information removed so that you cannot be recognised from it. Your samples and data may also be sent to these organizations out with the UK and EU. Before using your samples, all researchers must prove that they are following legal and ethical guidelines for their research. Any applications to use the samples will be reviewed by senior academic scientists to ensure the studies they are being used for are scientifically valid and justified. The research tissue bank has specific approved guidelines and monitoring processes in place for this. In addition, researchers working abroad will be required to sign a form agreeing to follow the same rules and regulations which apply in the UK.

7.What information is being collected?
The results of tests on your blood for inflammation, the data from brain monitoring during the operation, information on brain and memory function as well as some general information relating to your physical health will be collected.

8.How is the information going to be used?
Information from all patients included in the study will be entered into a computer database. We will use the information to try to predict which factors make patients more at risk of developing confusion and memory problems after an operation. In the future this knowledge may help clinicians to prevent and treat these complications.

9.How secure is the information?
If you decide to take part all the information which will be collected about you during the study will be kept strictly confidential. Your study doctor and nurse will have access to your case notes as well as authorised personnel from the Board for data monitoring and audit purposes. You will be assigned a study number which will be used to label data and samples and therefore, although data and samples will be sent to the University of Glasgow for analysis, no identifiable personal information will leave the hospital. Any published report of the data would not identify you.
NHS Greater Glasgow and Clyde is the Sponsor for this study in the United Kingdom.
We will be using information from you and 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. NHS Greater Glasgow and Clyde will keep identifiable information about you for up to five years after the study has finished.

All information that is collected about you during the research will be kept confidential. Any of your information or samples that leaves the hospital will have your name and address removed so that you cannot be recognised from it. Your personal information will be kept on file and securely stored in NHS Greater Glasgow and Clyde and any surplus samples will be stored within the Research Biobank at the University of Glasgow as described above. All test results will be labelled with a code and not with any personal details so that all analyses will be carried out anonymously. All information which is collected about you during the research will be kept strictly confidential.

Your name and address will be removed from any information which leaves the hospital so that you cannot be identified. Certain individuals from NHS Greater Glasgow and Clyde and regulatory organisations may look at your medical and research records to check that the research study is being carried out to an appropriate standard. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details.

Your identity will always remain confidential, and all of your personal information will be processed in accordance with the Data Protection Act (2018) and the General Data Protection Regulations (2018).

10.What are the possible disadvantages or risks of taking part?
Venipuncture will be required to collect blood samples. For most people, needle punctures for blood sampling do not cause any serious problems. However, they may cause dizziness or bleeding, bruising, discomfort, infections, and/or pain at needle site.

Monitoring the electrical activity of the brain during your operation will be done using skin electrodes on your forehead. There is a small risk of pressure effects on the skin from the electrodes but careful electrode placement should minimise this risk.

Testing of brain and memory function can take some time but are not associated with any adverse effects and are often used routinely in clinical practice.

11.What are the possible benefits of taking part?
There would be no direct benefit to you from taking part in this study, however, information gained from the study would hopefully enhance knowledge of post operative confusion following a general anaesthetic.

12.How long does the research intervention last?
The final follow up will be approximately six months after the spinal surgery.

13.Who is organising and funding the research?
The study is sponsored by the NHS Greater Glasgow and Clyde and funded by a grant from the. NHS GGC endowment fund.

14.Who has reviewed this study?
The study has been reviewed by the NHS Scotland A Research Ethics Committee.

15.What if I have any concerns?
If you have a concern about any aspect of this study please contact the study co-primary investigator Dr. Malcolm Watson (Consultant in Anaesthesia) on 0141 452 3430 or E-mail malcolm.watson@ggc.scot.nhs.uk Dr Malcolm Watson. For an independent view from a clinician not involved in the study you can contact Dr. Malcolm Sim (Consultant in Anaesthesia and Intensive Care medicine) on 0141 452 3033 or E-mail malcolm.sim@ggc.scot.nhs.uk

They will do their best to answer your questions.

If you remain unhappy the usual NHS complaints mechanisms will still be available to you and your relative. This can be accessed thought the Citizens Advice bureau, or the Boards complaints office on 0141 201 4500 (Email:complaints@ggc.scot.nhs.uk).