King's College Hospital NHS
NHS Foundation Trust

Project Title:

Physical effects and emotional experiences of intraoperative neuro-monitoring

Institutions

Department of Anaesthesia
Kings College Hospital, London.

Health Research Authority Approval

REC Reference: 18/SC/0193, IRAS Project ID: 239002

Correspondence

Chula Goonasekera chula.goonasekera@nhs.net

Date 20/11/2017

(Parent name and address)

Parent information sheet

Title of Project:

PHYSICAL EFFECTS AND EMOTIONAL EXPERIENCES OF INTRAOPERATIVE NEURO-MONITORING (IONM)

Dear Parent,

We'd like to invite your child to take part in our research study. Joining the study is entirely up to you and your child, before you decide we would like you to understand why the research is being done and what it would involve for your child and you.

Why have I been invited?

We understand that your child is scheduled to undergo a brain/spinal surgical procedure soon, aided by IONM mapping. You and your child are invited to participate in this project by helping us with a short face-to-face interview based on a structured questionnaire before your child leave hospital following surgery.

IONM is a 'SAT NAV' used by neurosurgeons to prevent injury to normal structures during brain and spinal surgery. It involves the use of micro-currents under anaesthesia. We have launched this study to explore patient experiences following Intra-operative Neuro-monitoring (IONM). This includes children who are able to communicate their experiences.

What is the purpose of the study?

This is mainly to gather your child's personal emotional experience and postoperative sequel and any associations with the type of IONM used. Please see below more information about this project. We are keen to answer any questions you may have concerning the study.

Do I have to take part?

Your child's participation is entirely voluntary and you should not feel under any pressure to take part. In anticipation, we would like to thank you and your child for considering taking part. You and your child are free to discuss this information with anyone you wish including your family and friends. If you and your child agree, we will then ask you to sign the attached consent form. Your child may sign too if he/she is aged 16 and above. You are free to withdraw on behalf your child at any time, without giving a reason. This would not affect the standard of care your child receive.

What will happen to me if I take part?

Your child's participation would include a face-to-face, open ended question and answer session conducted by a medical student researcher for approximately 10-20 minutes. This will be conducted after your child's operation and before discharge from hospital. The time selected for this interview will be to suit you and your child's convenience and comfort.

We will then associate your child's clinical records with that of his/her experience and his/her recovery details, again gathered from your child's clinical notes at 28 days and 1-year following

surgery.

Your child's clinical records will be accessed to obtain information of his/her disease condition, anaesthesia, surgery and IONM details and his/her general health indicators. Please note that this information is accessed only by your child's direct clinical care team members engaged in this research study (i.e. anaesthetists, surgeons) and will be stored after de-identification using a unique code identifier. All information obtained this way will be handled only for this research purpose and held completely confidential.

What are the possible benefits of taking part?

This study will explore the relatively unknown area of emotional experiences of children under anaesthesia who undergo various types of neuro stimulation (IONM) and related post-operative sequelae. The results are expected to be novel and assist improve patient experiences and outcomes in the future. This shall have no direct influence in your child's clinical management.

What are the possible disadvantages and risks of taking part?

In our opinion, the only downside is the time involved in answering the questions.

Who is organising and funding this study?

The doctor in charge of this study is: Dr XXX, Consultant Anaesthetist.

The study is funded and is being sponsored by Hospital XXX.

There shall be no specific remuneration for the doctors involved in this study nor do they have any conflicts of interest. The study results will support a medical student defend an intercalated B Sc degree.

Who have been involved in this study?

The design of this study was based on the opinions and observations of your child's clinical care team, i.e. neurosurgeons, neuroanaesthetists and neurophysiologists of Hospital XXX.

They have played a major role in the development of this planned study and the interview guide. The medical students are also supervised by XXX School of Medicine teaching staff.

Who has reviewed this study?

All research in the xxx is looked at by an independent group of people, called a Research Ethics Committee, to protect your/your chilld's interests. This study has been reviewed and given favourable opinion by XXX Hospital Research Ethics Committee. It has also been approved by the Health Research Authority.

Expenses and Payments

There are no funds available for payments to those participating in this study.

What happens when the research study stops?

The data obtained will be scientifically analysed and published appropriately for wider benefit. This publication will be obtainable from the chief investigator if you are interested.
The information gathered will also be presented in medical conferences and published without any

identification of its participants.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to your study doctor who will do their best to answer your questions, Dr XXX . If you remain unhappy and wish to complain formally, you can do this through the hospital XXX complaints procedure by contacting your local Patient Advice Liaison Service (PALS) office. Details of your local office can be obtained by asking your study doctor, GP, telephoning your local hospital.

What will happen if I don't want to carry on with the study?

You are free to withdraw on behalf of your child from the study at any time; and if you would like to do so; please speak to your study nurse or doctor. Your decision to withdraw from the study will not affect the care you receive.

If you withdraw your consent;

Please tell us whether information collected about you may be used if you are happy with this. You can withdraw consent for all information collected to be destroyed where this is possible.

Will my taking part be kept confidential?

Yes. All data, and statements collected during your interview will be confidential and anonymized during thematic analysis and publication. Field notes made by the researchers will be de-identified using a unique identifier code allocated on the consent form. All paper material and electronic data will be stored under lock and key in the Department of XYZ XXX Hospital encrypted computers.

If you consent to take part in the research, any of the information collected about you/ your child may be inspected by the sponsor i.e. XXX Hospital (including representatives of the sponsor). These inspections are solely for the purposes of the research and analysing the results. Your records may also be looked at by the regulatory authorities or ethics committees to check that the study is being carried out correctly. Your name will not be used in any reports about the study and all data is stored in accordance with the principles of the Data Protection Act 1998.

Involvement of the General Practitioner/Family Doctor (GP)

Since this is an observational study your GP will not be informed of your involvement.

What will happen to the results of the research study?

These will be communicated within the relevant academic community in scientific conferences and publications.

Thank you

Thank you for considering taking part in the study, and for taking the time to read this information sheet. If you decide on behalf of your child to take part in the study, we would ask that you give your signed consent on the attached form.

Further information and contact details
Chief Investigator Dr XXX

Yours truly,