JUN 16, 2023

OPEN ACCESS

DOI:
dx.doi.org/10.17504/protocols.io.eq2ly7y3wlx9/v1

Document Citation: Christopher Hawthorne, Keenan Smith, Eric Jackson, Matthew Sheridan, Shona McKay, Malcolm Watson, Martin Shaw, Jonathan Cavanagh 2023. GP Letter. **protocols.io** https://dx.doi.org/10.17504/protocols.io.eq2ly7y3wlx9/v1

Created: Apr 18, 2023

Last Modified: Jun 16, 2023

DOCUMENT integer ID: 80695

GP Letter

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ABSTRACT

Letter to participant's General Practitioner for Predicting Cognitive Decline After Spinal Surgery (PROTECT).

Neuroprogressive and Dementia Research Network DATE

PROTECT

Sponsor: Ms Rebecca Jardine, Research Facilitator, Research and Innovation, NHSGG&C

Chief Investigator: Dr Christopher Hawthorne, Consultant Anaesthetist, Institute of Neurological Sciences, NHSGG&C

Patient name address and CHI.

The above patient has kindly agreed to take part in a clinical trial entitled:

Predicting cognitive decline after spinal surgery (PROTECT).

DESCRIPTION OF TRIAL. *This is a prospective, observational study examining the link between serum inflammatory biomarkers, depth of anaesthesia, and postoperative cognitive outcomes. The trial is enrolling patients aged 65 years or over, who are undergoing non-emergency spinal surgery at the Queen Elizabeth University Hospital. Participants will be asked to take part in cognitive assessments prior to their surgery and will be followed up both in the acute postoperative period, and 6 months postoperatively to detect postoperative delirium and postoperative cognitive dysfunction, respectively. Results of these assessments will be compared to pre- and post-operative serum inflammatory markers such as CRP, IL-1β and IL-6, as well as intra-operative processed EEG data to build a prognostic model for perioperative neurocognitive disorders.*

Patients enrolled in the PROTECT trial will be asked to bring a family member or friend with them to their pre-operative assessment, and to allow up to 2 hours additional time at that appointment for in-depth cognitive and mental health assessments.

Serum blood sampling will be structured to avoid the need for additional venepuncture above and beyond that required for the participant's scheduled surgery. Pre-operative samples will be taken from the peripheral venous cannula inserted for induction of anaesthesia, and postoperative samples will be taken with the participants routine postoperative bloods.

Participants in the PROTECT trial will receive routine intra-operative monitoring, including processed EEG in the form of the BIS (Covidien) depth of anaesthesia monitor.This consists of four electrodes, place on the participants forehead prior to induction of anaesthesia, which remain on throughout the operation and are removed at the end.These relay information to the anaesthetist about the nature of electrical activity within the brain, which the anaesthetist uses to titrate anaesthetic delivery.

After the surgery participants will be seen by members of our research team up to three times over the next 5 days, where they will be assessed for postoperative delirium, which is a routine complication of elective surgery in this population group. Where delirium is detected, our team will contact the participant's next of kin to let them know and ask if they're happy for their loved one to continue in the study.We'll also relay this information back to the clinical team.

6 months after the participant has had their surgery, they will be invited back to have the cognitive and mental health assessments which were performed before their surgery, repeated.

A copy of the participant information sheet is enclosed for your information. Should you have any questions regarding this study, please do not hesitate to contact the trial team on xxxxxxxxxxxx (Mon-Fri 0800-1700).

Yours sincerely,

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