University Hospitals Birmingham NHS Foundation Trust

UNIVERSITY OF BIRMINGHAM

INFORMATION SHEET

IRAS ID: 324684

Traumatic brain injury related changes in military veterans

Acute brain injury group

You are being invited to take part in a research study carried out by researchers from the University of Birmingham and University Hospitals Birmingham NHS Foundation Trust. Before you decide about taking part, it is important for you to understand why the research is being done, and what it will involve. Please take some time to read the following information carefully. Please ask the researcher who gave you this sheet if there is anything that is not clear or if you would like more information.

Thank you

What is the purpose of the study?

After head injury, some people develop long-term problems such as sight problems, loss of balance and potential psychiatric conditions such as depression, anxiety and aggression.

Head injury is difficult to diagnose but fortunately recent research shows that proteins (biomarkers) in the blood can be used to diagnose and predict recovery after head injury. Examining the eye is becoming a relatively easy and non-invasive way of assessing head injury since vision is also affected in head injury patients. It is possible that early changes in the eye after head injury may tell us how severe head injury is and whether patients will have long-term problems with their vision as a result.

Why have I been asked?

We are approaching people who recently had head injuries (within the last 14 days) and don't have previous problems with their vision (other than glasses).

We wish to determine if blood and saliva biomarkers along with visual assessments, mental health assessments and outcomes reported by patients based on what is important to you (patient reported outcome measures; PROMs) can be used to devise an advanced tool to detect changes after a brain injury and predict long-term outcomes.

We will look for biomarkers that change with time after brain injury in blood and saliva and link these with changes in the eye using specialised pictures of the back of the eye (retina) and optic nerve called optical coherence tomography (OCT) images.

We will take blood and saliva samples and test both central vision and side-vision (visual field), the eye focussing mechanism, and eye movements, as well as OCT pictures taken of the eyes within the first 14 days after head injury and again at 1, 6 and 12 months (3 follow-up visits in total) to see if early changes in the retina and optic nerve after head injury tell us how severe the injury is and whether there are any long-term visual problems. We will also perform mental health assessments through well-established clinical tests when you join the study, and then at 1, 6 and 12 months. PROMs will also be collected at enrolment and at 1, 3, 6, 9 and 12 months using a questionnaire which we will post to you to fill in and post back to us.

As part of the study, we will also be approaching military veterans who have been diagnosed with a traumatic brain injury and have been discharged into NHS care and don't have problems with their vision (other than glasses) and people who have never had an episode of brain injury and who don't have problems with their vision. We will compare our findings across the different groups recruited.

Do I have to take part?

No. It is up to you to decide whether or not to take part. You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we have already collected.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

What do I have to do?

If you agree to take part, you will be asked to sign a consent form. The research team will then contact you and check to see if you are eligible to take part in the study. If you are not, your data will be removed.

If you are eligible, all of the tests will be performed in the Outpatients department at The Queen Elizabeth Hospital (University Hospitals Birmingham).

We will then arrange the following stages:

<u>Clinical assessment during enrolment (when you join the study) and at Visit 1 (1 month after enrolment.):</u>

1. Test of central vision including reading letter chart, colour vision and visual contrast test, which will take around 15 minutes.
2. Pupil test, which will take around 2 minutes.
3. Side vision test, which will take around 15 minutes.
4. Eye focussing mechanism and eye movement tests, which will take less than 10 minutes.
5. Eye picture, which will take around 5 minutes.

6. Psychiatric assessment, which will involve an assessment of your social and occupational functioning (SOFAS) based on a scale of 1-100 which will be completed by a clinical researcher and will take around 15 minutes.
7. Patient reported outcome measures questionnaire, which should take around 30 minutes.
8. Blood and saliva sample collection

Clinical assessment during visits 2 and 3 (6 and 12 months after Visit 1):

1. Test of central vision including reading letter chart, colour vision and visual contrast test, which will take around 15 minutes.
2. Pupil eye test, which will take around 2 minutes.
3. Side vision test, which will take around 15 minutes.
4. Eye focussing mechanism and eye movement tests, which will take less than 10 minutes.
5. Eye picture, which will take around 5 minutes.
6. Psychiatric assessment will take around 15 minutes.
7. Blood and saliva sample collection
8. Patient reported outcome measures questionnaire, which should take around 30 minutes.

Patient reported outcome measures will be collected when you join the study and at 1, 3,6,9 and 12 months after you join the study. These can be filled in by you on paper and mailed to us in stamped addressed envelopes which we will provide.

All the tests we will use are common standard tests used in eye clinics.

The information we gather will be made available to the doctors treating you.

What are the possible benefits of taking part?

Participants will receive no direct benefit from participation in this study. However, we hope that an early detection of changes in eye structure and visual outcome after head injury may be of benefit to future patients with head injuries, allowing early access to potential treatments.

What are the possible risks and burdens of taking part?

Being involved in the study means that you will be required to attend four clinical visits and spend more time having the study tests when you are in hospital than if you were not involved. We estimate that the length of extra time you would spend in the study is under two hours for each visit.

We will do these tests at the same time as a routine appointment wherever possible. If an additional visit to the hospital is needed, we will refund travel expenses.

Taking blood using a needle is uncomfortable, can cause bruising and bleeding and sometimes fainting. Only trained staff will collect the blood samples. Saliva will be collected in a tube and is not invasive and should not cause any problems. We will use eye drops to dilate your eyes. This may mean that your eyes will be more sensitive to light and can take up to 6 hours to become normal. We recommend the use of sunglasses to minimise the impact of light to your eyes. We also recommend that you do not drive and that someone accompanies you. We will refund travel expenses.

During the study, it may be that a diagnosis of psychiatric problems is found. If so, we will refer you to your care team for further support. We will also give details of local voluntary organisations that can help.

What if something goes wrong?

Clinical care will be unaffected by this study. It is unlikely that there would be any problems caused by taking part in this research because, except for routine blood collection, all of the tests used are not invasive. However, if you wish to complain about any aspect of the way you have been approached or treated during the course of this study, the usual National Health Service complaints mechanisms are available to you through the patient advice and liaison service (details at the bottom of this document).

What are the Insurance Arrangements?

The University has in force a Public Liability Policy and/or Clinical Trials policy which provides cover for claims for "negligent harm" and the activities here are included within that coverage.

Will the study be kept confidential?

Yes. All information that is collected during the course of the research will be kept strictly confidential. Details will be kept in a locked filing cabinet in a locked office and on encrypted NHS and University computers and only accessed by the researchers conducting the study.

How will my information be handled?

We will need to use information from you and your medical records for this research project.

This information will include your:

- initials
- NHS number
- name
- contact details

- and information from your assessments and questionnaires

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

If you lose capacity to consent during the study, your data and samples that have already been collected will be kept and used as part of the study. However, we will seek consent from your personal consultee or professional consultee before continuing you in the study.

University Hospitals Birmingham NHS Foundation Trust will use your name, NHS and hospital numbers and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study.

What will happen to my samples?

Blood and saliva samples will be stored in lockable fridges/freezers at University Hospitals Birmingham or University of Birmingham. Any leftover blood and saliva samples will be used in future ethically approved research studies or samples will be stored for up to 10 years before being destroyed.

You can withdraw from the study at any time. Any information and samples already collected will be retained.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from **www.hra.nhs.uk/patientdataandresearch**
- by asking one of the research team
- by sending an email to dataprotection@contacts.bham.ac.uk

What will happen to the results of the study?

The results will be published in reports and journals and and presented at local and international research meetings. We will be happy to provide copies of published results. All results will be anonymous.

Who is organising and funding the research?

The study is sponsored and insured by the University of Birmingham and is funded by the Cabinet Office (Office for Veteran's Affairs).

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