Golden Hour Biomarkers after Brain Injury Study

PERSONAL CONSULTEE INFORMATION SHEET

REC reference number 13/WA/0399

Invitation to take part

We would like to invite your friend/relative to participate in this research project being undertaken by University Hospitals Birmingham NHS Foundation Trust and the University of Birmingham. We would like to know of any reasons why you think your friend/relative would not want to be included in this research study and we will, of course, respect their wishes. As soon as your friend/relative is conscious and capable of making independent choices, we will ask them directly whether they wish to carry on with the study.

Not participating will not disadvantage them in any way. Before you let us know their views and yours, it is important for you to understand why the research is being done and what their participation will involve.

Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. If you would like them to take part please let us know; also inform us if they have been involved in any other study during the last year.

Purpose of the Study

The study is designed to look in depth at what happens immediately after a traumatic injury or stroke; we aim to recruit patients who have sustained traumatic injuries, those who have suffered a head injury or a stroke. By measuring their response to injury over time it is hoped a treatment can be developed in the future that will speed up healing and recovery.

What will they be asked to do?

There are a number of areas of work:

1. *Background Data.*

   Details of their injury or stroke symptoms, past medical history and background will be recorded from their hospital notes and by asking them questions.

2. *Blood Samples.*
   Research staff will take a 28ml blood sample from them at different time points during the study. This equals about 2 tablespoons of blood. A maximum of 7 blood samples will be taken over the 12-month study period.

   The first blood sample is taken as soon as possible after their injury/onset of symptoms. The next two samples will be taken during the first three days they are in hospital. Another sample will be taken when they are discharged. The remaining samples will be taken at follow-up visits.

   Wherever possible these samples will be taken when other blood samples need to be taken for their routine care, to minimise any discomfort.

3. *Urine Samples.*
   Research staff will collect a 50ml urine sample from them at different time points during the study. A maximum of 6 urine samples will be taken over the 12-month study period.

   The first sample is taken when they are admitted to hospital. The next samples will be taken during the first three days they are in hospital. Another sample will be taken when they are discharged. The remaining samples will be taken at follow-up visits.

   These samples will be collected as standard of care and would normally be disposed of.

4. *Saliva Samples.*
   Research staff will take a swab of the inside of their mouth to collect a saliva sample. A maximum of 7 saliva samples will be taken over the 12-month study period.

   The first sample is taken as soon as possible after their injury/onset of symptoms. The next samples will be taken during the first three days they are in hospital. Another sample will be taken when they are discharged. The remaining samples will be taken at follow-up visits.

The sample schedule is detailed in the table below:

Sample Number	Time Point	Sample Collected
1	0 (point of injury/onset of symptoms)	28mls blood Saliva sample via mouth swab
2	Day 1 (UHB ED) (if no time 0 sample taken)	28mls blood Saliva sample via mouth swab 50mls urine
3	Day 1 (4-12 hours post injury)	28mls blood Saliva sample via mouth swab 50mls urine
4	Day 3	28mls blood Saliva sample via mouth swab 50mls urine
5	Day 1-14	5mls CSF and/or microdiasylate***
6	Day of Discharge from hospital**	28mls blood Saliva sample via mouth swab 50mls urine
7	Day 90 (+/-14 days)	28mls blood Saliva sample via mouth swab 50mls urine
8	Day 180 (+/-30 days)	28mls blood Saliva sample via mouth swab 50mls urine

Sample Number	Time Point	Sample Collected
9	Day 365 (+/-30 days)	28mls blood Saliva sample via mouth swab 50mls urine

*If you are discharged from hospital before Day 3, we will not collect sample number 4

**Within 7days of discharge

*** If taken as part of clinical care

5. *Cerebrospinal fluid (CSF) collection*.
   This is the fluid that surrounds the brain and spinal cord. If your relative/friend needs to have a sample of this taken during their routine care, then we will request an additional 5ml sample be taken at the same time. This amount is relatively small and will not add to the existing small risk of the procedure. We will not take a sample for research unless your relative/friend needs to have one for clinical purposes.

The blood, urine, saliva and, if taken the CSF, tests will look at markers of traumatic injury, head injury or stroke and we hope to gain a better understanding of what happens to our bodies following these injuries. These analyses may include genetic testing for genes that may affect outcome after brain injury. Like the other tests, genetic analysis will be treated in the strictest confidence and will only be used for the purposes of this study. They will not become part of your friend's/relative's health records.

6. *Microdialysis.*
   Some patients who have head injuries may have a probe placed in their head to monitor the pressure surrounding the brain. A small tube in the probe takes measurements of the chemical composition of the brain itself. As part of this process fluid is leftover and normally disposed of. If your relative/friend needs to have a probe placed, we will retain the fluid for analysis of the chemicals in it. A probe will not be placed unless required for their normal treatment.

7. *Magnetic Resonance Scans*.
   Some people in our study will be asked to undergo scans in addition to those carried out as part of normal treatment. Routine scans cannot always show brain injuries in enough detail and we want to assess newer ways of performing brain scans to see if these will guide diagnosis and treatment better in the future. Mostly we would ask for two scans, the first in month 1 and another at 6 months. Only a few people may be asked to come back after 1 year. The scans are safe and do not involve any radiation. We will give you further information if we would like your relative/friend to have these additional scans.

8. *Health Questionnaires.*
   As part of your relative's/friend's treatment we use a range of questionnaires which help to diagnose and categorise injuries and also chart progress and recovery. In addition to the standard questionnaires used in the hospital we would ask your relative/friend to complete some extra ones. These include questionnaires to report symptoms that your friend/relative may be experiencing, any difficulties with day-to-day tasks, any

issues with low mood or anxiety issues, and any factors affecting quality of life. For additional safety, if the questionnaires should flag up that your friend/relative may be experiencing risky levels of anxiety or depression, we will ask their GP to make contact with them to discuss the necessary course of action.
We can get some of this information from the health records, e.g. via your relative's/friend's GP. The rest of the information can be collected by self-reporting questionnaires, which can also be completed with the help of a close friend or relative. We will collect this information around 3, 6 and 12 months after the initial event. This will help us better understand the injury and its impact.

9. *Follow-Up*.
We will try to take samples and arrange scans in Outpatients when your relative/friend comes to follow-up appointments after they have left hospital. As this is not always possible, we may need to contact your relative/friend by letter, email or telephone if any extra appointments are needed for the study. We will arrange these at a time convenient to your relative/friend. Travel expenses or hospital transport will be made available to them. They are under no obligation to accept these appointments and refusal will not affect their care.

What are the benefits of taking part?

The benefits for your relative/friend as an individual are small, although they will have additional tests and possibly scans, not enough is yet known about these to substantially change their treatment. Although there will not be any benefits to their treatment, this work will help to develop ways to improve diagnosis and treatment for patients with head injuries or stroke in the future.

What are the possible disadvantages and risks of taking part?

The risks of participation are small. Where blood tests are required, the risks are identical to normal clinical tests. MRI scans are not known to have any adverse effects, although they involve lying still for a prolonged period of around 40 minutes which may be uncomfortable.

You are free to withdraw your relative/friend from the study at any time without giving a reason. If you ever require any further information or explanation, please do not hesitate to ask.

How will we use information about the patient?

We will need to use information from the patient's medical records for this research project. This information will include name, NHS number, date of birth, sex, ethnicity, general admission details and clinical data about the hospital stay. People will use this information to do the research or to check records to make sure that the research is being done properly. People who do not need to know who the patient is will not be able to see the name or contact details; instead, data will be saved with a code number. We will keep all information about the patient 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 nobody can work out that they took part in the study.

What are your choices about how the patient's information is used?

The patient can stop being part of the study at any time, without giving a reason, but we will keep the information about them that we already have. If the patient should choose to stop taking part in the study, we would like to continue collecting information about their health from the hospital. If you deem that the patient does not wish for this to happen, tell us and we will stop. 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 the patient see or change the data we hold about them.

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

You can find out more about how we use your information by:

- Visiting www.hra.nhs.uk/information-about-patients/
- Contacting the research team on: 07747 101720 or 0121 371 4242
- Contacting:

The Data Protection Officer
Legal Services
The University of Birmingham
Edgbaston
Birmingham B15 2TT

Email: dataprotection@contacts.bham.ac.uk
Telephone: 0121 414 3916

Confidentiality

Your relative's/friend's identity will remain confidential throughout the study. Other information, from which they could not be identified, will be published or presented with the aim of benefiting others. You may request copies of all papers, reports, transcripts, summaries and other published material. All information is subject to the conditions of the Data Protection Act 2018 and the General Data Protection Regulation.

Will taking part or not taking part affect the medical care of my next of kin?

You should only agree to your relative/friend participating if you want to or if you think they would not object to do so. Choosing not to take part will not disadvantage your relative's/friend's medical care in any way.

What if there is a problem?

If you have a concern about any aspect of this trial, you should contact the REACT (Research in Emergency and Acute Care Team) who will do their best to answer your questions. You can use the contact number at the end of this sheet.

If you remain unhappy and wish to complain formally, you can do this through the hospital's Patient Advice and Liaison Service on 0121 371 3280, or email PALS@uhb.nhs.uk.

In the event that something does go wrong and the patient is harmed during the trial there are no special compensation arrangements. If the patient is harmed and this is due to someone's negligence, then you may have grounds for legal action for compensation against the University of Birmingham but you may have to pay your legal costs. NHS Trust and Non-Trust Hospitals have a duty of care to patients treated, whether or not the patient is taking part in a clinical trial and the normal NHS complaints mechanisms will still be available to you (if appropriate).

What will happen to any samples collected?

Your relative's/friend's samples will be assigned a code, and then transported to the University of Birmingham and Marker Health (hosted within the University of Birmingham) whom we collaborate with for analysis. They will not be identifiable; only the Chief Investigator and Research Team retain the code to link you with your samples. Once analysis of the samples has been completed all samples will be kept (with their cells removed) for 15 years and then destroyed.

Optional consent will be sought for us to keep anonymised data and samples for use in future ethically approved projects in the United Kingdom or the European Union. These may be shared with industrial partners. You will not benefit financially from this.

If your relative/friend loses capacity or dies during the course of the study, the research team will retain their personal data and samples already collected and will continue to use them for the sole purposes for which consent was sought.

What happens if I want to withdraw them from the study?

Your relative/friend is under no obligation to continue in the study. Withdrawal from the study will not affect their medical care in any way. The data and samples held by the Research Team belong to your relative/friend and as such, you may have those samples and identifiable data removed from the study at any time. Where anonymous data has been compiled into results this cannot be removed.

Who is organising and funding the research?

This study is being funded by the Medical Research Council and the Stroke Association.

All research in the UK is looked at by an independent group of people, called a Research Ethics Committee. Research Ethics Committees (RECs) safeguard the rights, safety, dignity and well-being of people participating in research. They review applications for research and give an opinion about the proposed participant involvement and whether the research is ethical. This study has been reviewed and given a favorable opinion by the North Wales Research Ethics Committee – West.

Who is sponsoring and insuring this study?
The University of Birmingham (UoB) is the sponsor for this study based in the United Kingdom. The University of Birmingham has in place Clinical Trials indemnity coverage for this trial which provides cover to the University for harm which comes about through the University's, or its staff's, negligence in relation to the design or management of the trial and may alternatively, and at the University's discretion provide cover for non-negligent harm to participants.

With respect to the conduct of the trial at Site and other clinical care of the patient, responsibility remains with the NHS organisation responsible for the clinical site and is therefore indemnified through NHS Resolution. The University of Birmingham is independent of any pharmaceutical company, and as such it is not covered by the Association of the British Pharmaceutical Industry (ABPI) guidelines for participant compensation. The NHS have a duty of care to participants whether or not the participant is taking part in a clinical trial and the normal NHS complaints mechanisms will still be available to you.

Confidentiality
University Hospitals Birmingham NHS Foundation Trust will keep their name, NHS number, contact details and other identifiers confidential. University Hospitals Birmingham NHS Foundation Trust will use this information as needed, to contact them about the research study, and make sure that relevant information about the study is recorded for their care, and to oversee the quality of the study. Certain individuals from the Sponsor organisation and regulatory organisation may look at their medical and research records to check the accuracy of the research study. The Sponsor organisation will only receive information without any identifying information. The people who analyse the information will not be able to identify your friend/relative and will not be able to find out their name, NHS number or contact details.

University Hospitals Birmingham NHS Foundation Trust will keep identifiable information about them from this study for 15 years after the study has finished.

If you would like more information on your rights, would like to exercise any right or have any queries relating to our processing of your personal data, please contact:

The Information Compliance Manager
Legal Services
The University of Birmingham
Edgbaston
Birmingham
B15 2TT

Email: dataprotection@contacts.bham.ac.uk
Telephone: +44 (0)121 414 3916

If you wish to make a complaint about how your data is being or has been processed, please contact our Data Protection Officer:

The Data Protection Officer
Legal Services
The University of Birmingham
Edgbaston
Birmingham
B15 2TT

Email: dataprotection@contacts.bham.ac.uk
Telephone: +44 (0)121 414 3916

You also have a right to complain to the Information Commissioner's Office (ICO) about the way in which we process your personal data. You can make a complaint using the ICO's website (https://ico.org.uk/make-a-complaint/) or call their helpline on 0303 123 1113.

Thank you for reading this information sheet.

Other Contacts

Chief Investigator:

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