Golden Hour Biomarkers after Brain Injury Study (Golden Hour)

REC reference number 13/WA/0399

PATIENT INFORMATION SHEET
(after regaining capacity)

When you were first admitted to hospital, we asked either a Personal or Nominated Consultee whether you would have any objection to taking part in the following research study. A Personal Consultee is either a relative or a friend and a Nominated Consultee is a medical professional independent to the research study. We have sought advice from either one of these people as you were not well enough to give consent yourself.

Now you are able, we would like to give you some more information about the study to help you decide whether you would like to continue in the research.

One of our team will go through the information leaflet with you and answer any questions you may have. We'd suggest this should take about 30 minutes. Please ask us if anything is unclear or if you would like more information.

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, a head injury or a stroke. By measuring your response to injury overtime, it is hoped a treatment can be developed in the future that will speed up healing and recovery.

What will I be asked to do?

There are a number of areas of work:

1. *Background Data.*

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

2. *Blood Samples.*
   Research staff will take a 28ml blood sample from you 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 your injury/onset of symptoms. The next two samples will be taken during the first three days you are in hospital. Another sample will be taken when you 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 your routine care, to minimise any discomfort.

3. *Urine Samples.*

Research staff will collect a 50ml urine sample from you 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 you are admitted to hospital. The next samples will be taken during the first three days you are in hospital. Another sample will be taken when you 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 your 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 your injury/onset of symptoms. The next samples will be taken during the first three days you are in hospital. Another sample will be taken when you 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 or onset of symptoms)	28mls blood Saliva sample via mouth swab
2	Day 1 (UHB ED) (if no time 0sample 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 (+/-30days)	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 7 days 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 you need to have a sample of this taken during your treatment, then we will request an additional 5ml sample to 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 you need 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 health records.

6. *Microdialysis.*
   Some patients who have head injuries have a probe placed in their head to monitor the pressure surrounding the brain to aid in their treatment. As well as the pressure, a small tube in the probe allows measurements of the chemical composition of the brain itself. As part of this process fluid is leftover and normally disposed of. If you need to have a probe placed, we will recover the fluid for analysis of the chemicals in it. A probe will not be placed unless required for your 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 one year. The scans are safe and do not involve any radiation. We will give you further information if we would like you to have these additional scans.

8. *Health Questionnaires.*
   As part of your 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 you to complete some extra ones. These include questionnaires to report symptoms that you 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 you may be experiencing risky levels of anxiety or depression, we will ask your GP to make contact with you to discuss the necessary course of action. We can get some of this information from the health records, e.g. via your 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 your injury and its impact on you.

9. *Follow-up Session*.
   We will try to take samples and arrange scans in Outpatients when you come to follow-up appointments after you have left hospital. As this is not always possible, we may need to contact you by letter, email or telephone if any extra appointments are needed for the study. We will arrange these around you. Travel expenses or hospital transport will be made available to you. You are under no obligation to accept these appointments and refusal will not affect your care, although we ask that you let us know if you can't make it.

What are the benefits of taking part?

The benefits for you as an individual are small, although you will have additional tests and possibly scans not enough is yet known about these to substantially change your treatment. Although there will not be any benefits to your 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 may at any time withdraw from the study 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 you?

We will need to use information from your medical records for this research project. This information will include your name, NHS number, date of birth, sex, ethnicity, general admission details and clinical data about your hospital stay. 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 nobody can work out that you took part in the study.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. If you choose to stop taking part in the study, we would like to continue collecting information about your health from your hospital. If you do not want 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 you see or change the data we hold about you.

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: 07747101720 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 identity will remain confidential throughout the study. Other information, from which you 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 (GDPR).

Will my taking part or not taking part affect my medical care?

You should only participate if you want to; choosing not to take part will not disadvantage you in any way regarding your medical treatment.

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 you are harmed during the trial there are no special compensation arrangements. If you are 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 I give?

Your blood samples will be assigned a code, and then transported to the University of Birmingham and University of Birmingham and Marker Health (hosted within the University of Birmingham) whom we collaborate with for analysis. They will not be identifiable to you; 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 you lose capacity or die during the course of the study, the research team will retain your 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 from the study?

You are under no obligation to continue in the study. Withdrawal from the study will not affect your medical care in any way. The data and samples held by the Research Team belong to you 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 insuringthis 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 your name, NHS number, contact details and other identifiers confidential. University Hospitals Birmingham NHS Foundation Trust will use this information as needed, 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. Certain individuals from the Sponsor organisation and regulatory organisation may look at your 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 you and will not be able to find out your name, NHS number or contact details.

University Hospitals Birmingham NHS Foundation Trust will keep identifiable information about you 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:

Mrs Carolyn Pike, OBE
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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