Point of care testing in emergency departments after mild traumatic brain injury

Clinician Information Sheet

Head injury is a common Emergency Department (ED) presentation, but only a small proportion of patients undergoing CT have clinically significant traumatic brain injury (TBI).

This study aims to evaluate how point-of-care brain injury biomarkers could be safely and effectively integrated into routine care in patients who present with a head injury to UK Emergency Departments.

Following a brain injury, specific proteins (biomarkers) are released in to the blood. Two such biomarkers - **GFAP** (a marker of glial injury) and **UCH-L1** (a marker of neuronal injury) - can be measured using a point of care device. In this study we are using the Abbott i-STAT Alinity point-of-care device.

These biomarkers may help to inform:

1) Decisions about CT imaging (diagnosis)
2) Improve identification of patients who are at risk of symptoms persisting for months after injury (prognosis).

Biomarkers are not currently recommended for use in the NICE Head Injury Guidelines [NG232] and need more evidence of clinical utility, safety and cost-effectiveness.

Who will be recruited?

- Patients ≥18 years who present within 24 hour of sustaining a head injury that needs assessment for a CT head using NICE Head Injury Guidelines (NG232) and have a GCS of 13, 14 or 15. We are being as pragmatic as possible with recruitment to ensure the patients reflect those who we see in our clinical practice.

Why are we aiming to recruit patients before they have their CT head?

- Most previous studies have collected biomarker samples **after CT imaging**, limiting our ability to determine whether biomarkers could safely reduce CT use in routine practice.
- Recruiting patients **before CT** reflects how biomarkers would be used in real ED workflows and allows a robust evaluation of safety, feasibility and potential impact in an NHS setting.

Why are we taking bloods at 2 time points (two hours apart)?

- To understand whether change over time is more informative than a single measurement
- To allow for two sets of biomarkers in patients who do not have a CT which allows for observation time and information to inform future safe use given biomarkers are not currently part of routine clinical practice.
- We will be storing these blood to enable later analysis of a wider range of candidate biomarkers.
- We recognise that participation in this study may delay discharge for a very small number of patients. We are grateful to the clinical teams facilitating recruitment and to the patients taking part, and we hope that the evidence generated will help reduce emergency department length of stay for future patients.

What might I need to do?

- You may be asked to give consent as a Professional consultee where a patient does not have capacity and there are no next-of-kin present. We will gain consent from the patient/NoK as soon as possible after.
- **Please manage the patient as you would usually** in line with the NICE Head Injury Guideline [NG232] and standard clinical practice. We are not aiming to change practice in this observational study.
- After a decision for CT or not has been made you may be shown the Point of Care biomarker results with an explanation of how to interpret them. The research team may ask 3 short questions about how this may change what you do in future practice. Thank you for answering these.

What else are we asking patients to do?

- Where possible patients will fill in some short questionnaires in the Emergency Department. We will then follow them up by phone/mail/online at ~2 weeks, 3months and 6 months with a set of questionnaires and neurocognitive tests. The core outcome measures take about15 minutes to complete.
- Patients will be sent a £20 voucher at the end of study as a token of appreciation for their time and contribution to the study.

If there are any questions or you wish to find out more please contact:
https://www.tbiresearch.co.uk/pocket-information-for-clinicians
Study team (pocket.study@uea.ac.uk), Chief Investigator Virginia Newcombe (vfjn2@cam.ac.uk) or Co-Lead Fiona Lecky (f.e.lecky@sheffield.ac.uk)

Which patients are eligible for recruitment?

Inclusion Criteria:	Exclusion criteria:
• Adult patients (≥ 18 years of age) and • Glasgow Coma Score >12 and • Presentation within 24 hours of head injury and • Meet criteria to be assessed for whether they need a CT head after a head injury using the NICE Guidelines (NG232).	• Participant without capacity and no available personal or professional consultee. • Participant with capacity unwilling to provide informed consent • Unable to adequately understand written and verbal English. • Prisoners currently in custody of HM Prison Service

Please note only patients 18 and over are being recruited. For information below is the NICE algorithm for selecting patients head CT.