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Measuring brain injury markers (GFAP and UCH-L1) to predict concussion

Submission date	Recruitment status	[_] Prospectively registered
23/05/2025	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
11/06/2025	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
05/11/2025	Injury, Occupational Diseases, Poisoning	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Glial fibrillary acidic protein (GFAP) and ubiquitin carboxyl-terminal hydrolase L1 (UCH-L1) have been shown to be released in people who have suffered from severe head injuries that show up on brain scans.
These markers have been used as a rule-out test for Computerised Tomography (CT) scans in patients presenting with head injuries. However, the low specificity of the test means that they are raised in many patients with a normal CT scan. This same study showed that patients with higher biomarker levels had poorer outcomes at 3 months.
Concussion is often underdiagnosed in athletes and the general population, resulting in poor management and prolonged recovery. Undiagnosed concussion could present a danger to athletes participating in sports requiring a high level of concentration, such as motorbike racing. We suspect that patients who have elevated levels of GFAP and UCH-L1 may have a greater incidence of concussion and should undergo screening for a safe return to sport.
This study aims to see if there is a correlation between raised brain injury markers (GFAP and UCH-L1) and symptoms of concussion in patients with a normal CT of their head following head injury.

Who can participate?
Competitors in the 2025 Isle of Man TT who are injured during a race or practice session and require a CT scan of their head but are able to give consent

What does the study involve?
Blood samples will be taken to measure GFAP and UCH-L1 and participants will be followed up 2 weeks later to perform the Sports Concussion Assessment Tool (Version 6).

What are the possible benefits and risks of participating?
No obvious risks or benefits to participants

Where is the study run from?
Noble's Hospital (Isle of Man)

When is the study starting and how long is it expected to run for?
May 2025 to June 2025

Who is funding the study?
1. Manx Care (Isle of Man)
2. Isle of Man Medical Research (Isle of Man)

Who is the main contact?
Dr David Frazer, david.frazer@nobles.dhss.gov.im

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
173

Study information

Scientific Title
Measurement of glial fibrillary acidic protein (GFAP) and ubiquitin carboxyl-terminal hydrolase L1 (UCH-L1) to predict symptoms of concussion in high-energy trauma

Study objectives
Can measurement of glial fibrillary acidic protein (GFAP) and ubiquitin carboxyl-terminal hydrolase L1 (UCH-L1) predict symptoms of concussion in high energy trauma?

Ethics approval required

Ethics approval required

Ethics approval(s)
approved 12/05/2025, Isle of Man Research Ethics Committee (Public Health Directorate Cabinet Office, Isle of Man Government, Strang, IM4 4RJ, Isle of Man; +44 (0)1624 685765; adam.dempsey@gov.im), ref: 174

Study design
Single-centre diagnostic evaluation study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Concussion

Interventions
The patient has fallen off a motorcycle and is having a computerised tomography scan of their head to assess injury. They must be conscious and able to provide consent. Blood taken as part of their routine management is also tested for measurement of glial fibrillary acidic protein (GFAP) and ubiquitin carboxyl-terminal hydrolase L1 (UCH-L1). CT head is performed. 2-3 weeks later they are contacted to undergo screening for concussion using a questionnaire from the Sports Concussion Assessment Tool (version 6) and the score is correlated with the results of the brain injury markers.

Intervention Type
Other

Primary outcome(s)
1. Glial fibrillary acidic protein (GFAP) and ubiquitin carboxyl-terminal hydrolase L1 (UCH-L1) measured using blood test using Abbott i-STAT GFAP/UCH-L1 cartridge point of care testing at time of arrival in the emergency department
2. Screening for concussion using a questionnaire from the Sports Concussion Assessment Tool (version 6) at 2 to 3 weeks following injury by telephone

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
08/06/2025

Eligibility

Key inclusion criteria
Competitors in the 2025 Isle of Man TT who are injured during a race or practice session and require a CT scan of their head

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Unable to give consent

Date of first enrolment
25/05/2025

Date of final enrolment
08/06/2025

Locations

Countries of recruitment
Isle of Man

Study participating centre
Noble's Hospital
Emergency Department
Strang
Isle of Man
IM4 4RJ

Sponsor information

Organisation
Manx Care

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Manx Care

Funder Name
Isle of Man Medical Research

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans are currently unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file			27/05/2025	No	No