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

Submission date 23/05/2025	<b>Recruitment status</b> No longer recruiting	<ul><li>Prospectively registered</li><li>[X] Protocol</li></ul>
<b>Registration date</b> 11/06/2025	<b>Overall study status</b> Completed	<ul> <li>Statistical analysis plan</li> <li>Results</li> </ul>
Last Edited 27/05/2025	<b>Condition category</b> Injury, Occupational Diseases, Poisoning	<ul><li>Individual participant data</li><li>[X] Record updated in last year</li></ul>

## 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 soo if there is a correlation between raised brain injury markers (CEAP and

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? Manx Care (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

**Contact name** Dr David Frazer

## **Contact details**

Emergency Department Noble's Hospital Strang Isle of Man IM4 4RJ +44 (0)1624650366 david.frazer@gov.im

# Additional identifiers

**EudraCT/CTIS number** Nil known

#### **IRAS number**

**ClinicalTrials.gov number** Nil known

Secondary identifying numbers 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

**Secondary study design** Case series

**Study setting(s)** Other

**Study type(s)** Diagnostic

**Participant information sheet** Not available in web format

#### 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 measure

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

#### Secondary outcome measures

There are no secondary outcome measures

#### Overall study start date

12/05/2025

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

**Age group** Adult

**Sex** Both

**Target number of participants** 30

**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

Sponsor details

Emergency Department Strang Isle of Man IM4 4RJ +44 (0)1624650366 Lesley.Clyde@nobles.dhss.gov.im

**Sponsor type** Hospital/treatment centre

Website

https://www.gov.im/about-the-government/statutory-boards/manx-care/

# Funder(s)

Funder type Hospital/treatment centre

**Funder Name** Manx Care

# **Results and Publications**

**Publication and dissemination plan** Planned publication in a peer reviewed journal

Intention to publish date 01/06/2026

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?
<u>Protocol file</u>			27/05/2025	No	No