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Head injury evaluation and ambulance diagnosis to avoid hospital emergency admission: A HOME feasibility study

Submission date
13/09/2022

Recruitment status
No longer recruiting

Registration date
11/01/2023

Overall study status
Completed

Last Edited
25/06/2024

Condition category
Injury, Occupational Diseases, Poisoning

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Traumatic Brain Injury (TBI) is widely recognised as one of the most common causes of death and disability, primarily among young adults, and is getting more frequent in the older population. It is a widely held view that TBI is a pathophysiological heterogeneous condition that varies widely in terms of aetiology, severity, clinical presentation and outcomes. This spectrum of severity creates clinical challenges, as many patients with mild TBI may be admitted to a major trauma centre (MTC), resulting in overwhelming MTC resources with minor injuries.

Various validated clinical tools have been developed to determine the need for a CT scan to rule out intracranial lesions in adult patients with a minor head injury. Of these, the Canadian CT head rule (CCHR) was developed through a series of prospective studies involving thousands of patients to determine the need for neuroimaging. CCHR is a highly sensitive rule to assist clinicians in identifying patients with clinically significant head injuries who should undergo CT scanning.

To obtain precise estimates for the diagnostic accuracy of the CCHR that could be used to change clinical practice is likely to require a large, multi-centre study. This would be expensive and time-consuming. Successful delivery of the research would also depend heavily upon adherence to the study protocol, recruitment rate and attrition. Before embarking on such a large study, therefore, it is prudent to evaluate the feasibility of the intended study processes.

Who can participate?
A convenience sample of adult patients with mild TBI

What does the study involve?
Feasibility outcomes will be assessed using screening logs and case report forms completed by paramedics during the course of the study. At the receiving hospital, emergency physicians will assess the patients to determine whether a CT scan is necessary, which may involve using the CCHR. Clinicians at the receiving hospitals will be asked to assess the patients using the CCHR and record their findings to determine inter-observer reliability. We will evaluate the

acceptability of the CCHR among participating paramedics. Additionally, we will evaluate the acceptability of trial processes to patients and paramedics using a qualitative approach.

What are the possible benefits and risks of participating?
There are no immediate benefits for individuals who participate in this study. We anticipate that the findings of this study will help to improve the care we provide in the future by providing clinical evidence to conduct further studies in this area. It is unlikely that patients will be at high-risk during this study.

Where is the study run from?
Manchester Royal Infirmary (United Kingdom)

When is the study starting and how long is it expected to run for?
March 2022 to December 2023

Who is funding the study?
The University of Manchester (United Kingdom)

Who is the main contact?
Naif Alqurashi (United Kingdom)
naif.alqurashi@postgrad.manchester.ac.uk

Contact information

Type(s)
Principal investigator

Contact name
Prof Richard Body

Contact details
Emergency Department,
Manchester Royal Infirmary
Oxford Rd, Manchester
United Kingdom
M13 9WL
01612765071
richard.body@manchester.ac.uk

Type(s)
Scientific

Contact name
Mr Naif Alqurashi

Contact details
Division of Cardiovascular Sciences, Faculty of Biology, Medicine, and Health
Manchester
United Kingdom

M13 9WL
01612765071
naif.alqurashi@postgrad.manchester.ac.uk

Additional identifiers

Integrated Research Application System (IRAS)
316547

Protocol serial number
IRAS 316547

Study information

Scientific Title
Head injury evaluation and ambulance diagnosis to avoid HOspital eMErgency admission: A HOME feasibility study

Acronym
HOME Study

Study objectives
The purpose of this study is to establish the feasibility of a fully powered diagnostic test accuracy study to evaluate the accuracy of the Canadian CT head rule when applied by paramedics in the prehospital setting in patients with head injuries

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 15/12/2022, North West – Greater Manchester (GM) South (3rd Floor Barlow House, 4 Minshull Street, HRA NRES Centre, Manchester, M1 3DZ, UK; +44 (0)207 104 8014; approvals@hra.nhs.uk, HCRW.approvals@wales.nhs.uk), ref: 22/NW/0358

Study design
Prospective multi-centre feasibility study

Primary study design
Observational

Study type(s)
Screening

Health condition(s) or problem(s) studied
Mild traumatic brain injury

Interventions
The purpose of this study is to establish the feasibility of a fully powered diagnostic test accuracy study to evaluate the accuracy of the Canadian CT head rule (CCHR) when applied by paramedics in the prehospital setting in patients with head injuries.

The CCHR was developed through a series of prospective studies involving thousands of patients to determine the need for neuroimaging. It helps to identify clinically important brain injuries on CT scans that may require neurosurgical intervention. The rule consists of five high-risk clinical factors for neurosurgical intervention, and two medium-risk factors for predicting brain injury on a CT scan and takes into account a number of variables related to the patient's medical history and physical examination. All of the data required for the CCHR are available to paramedics in the prehospital environment. Therefore, it may be possible to apply the CCHR based on prehospital information obtained at the scene. Before embarking on such a large study, therefore, it is prudent to evaluate the feasibility of the intended study processes.

A prospective, multi-centre pilot feasibility diagnostic accuracy study will be conducted. A convenience sample of adult patients with mild traumatic brain injury will be transported to study site hospitals. Once the paramedics determine that a patient meets the inclusion criteria, they will be asked to assess the patients in the ambulance using the CCHR and record their interpretation of the decision aid using a paper CRF prior to arriving at a study site hospital. Emergency physicians at the receiving hospitals will be asked to assess the patients using the CCHR and record their findings to determine inter-observer reliability.
- Feasibility outcomes will be examined.
- We will measure paramedics' attitudes toward the CCHR will be used to evaluate the acceptability of the CCHR.
- We will evaluate the acceptability of trial processes to patients and paramedics using a qualitative approach to obtain their perspectives regarding their participation and experiences in the trial.

Intervention Type
Other

Primary outcome(s)
Feasibility outcomes:
1. Number of eligible patients approached measured using screening logs and case report forms throughout the enrolment period
2. Proportion of patients approached who consent to participate in the study measured using screening logs and case report forms throughout the enrolment period
3. Completeness of data collection measured using screening logs and case report forms throughout the enrolment period
4. Completeness of follow-up measured using case report forms following hospital discharge or death (if in-hospital)
5. Determination of the inter-observer reliability of the Canadian CT head rule completion between prehospital care providers (during the prehospital phase) and ED physicians (while patients are in the Emergency Department) measured using case report forms
6. Determination of the inter-observer reliability of each component of the Canadian CT head rule between prehospital care providers (in the prehospital phase) and ED physicians (while patients are in the ED) measured using case report forms
7. The diagnostic performance of the Canadian CT head rule, as assessed by paramedics in the prehospital phase, using patient records and case report forms
8. The acceptability of trial processes to patients and paramedics measured using a qualitative approach and clinical sensibility of the Canadian CT head rule measured using a survey method

Key secondary outcome(s))

Presence of traumatic intracranial lesion requiring neurosurgical intervention, defined as any neurosurgical intervention and/or abnormal head CT findings and/or death within 7 days as a result of traumatic brain injury measured using medical records at 7 days after initial admission

Completion date
01/07/2024

Eligibility

Key inclusion criteria
1. Adult patients aged 16 years old and over who receive an emergency ambulance response for a primary complaint of head injury
2. Glasgow coma scoring (GCS) of 13–15 at the time of assessment by treating paramedics
3. Patients who will be transported to the hospital as part of their routine clinical care

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
16 years

Sex
All

Key exclusion criteria
1. Already received care in hospital for their condition and who are undergoing secondary transfer to a specialist centre
2. Penetrating skull injury
3. Trauma to other body regions that would require transport to the hospital
4. Prisoners

Date of first enrolment
01/09/2023

Date of final enrolment
01/05/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
North West Ambulance Trust Hq
Ladybridge Hall
399 Chorley New Road
Bolton
United Kingdom
BL1 5DD

Study participating centre
Manchester University NHS Foundation Trust - Comcov3 Covid19 Trials
Manchester Royal Infirmary
Oxford Road
Manchester
United Kingdom
M13 9WL

Study participating centre
Northern Care Alliance NHS Foundation Trust
Salford Royal
Stott Lane
Salford
United Kingdom
M6 8HD

Sponsor information

Organisation
University of Manchester

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
University/education

Funder Name

University of Manchester

Alternative Name(s)
The University of Manchester, University of Manchester UK, University of Manchester in United Kingdom, UoM

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are 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?
Protocol article		11/06/2024	25/06/2024	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	version 2.0	20/11/2022	20/12/2022	No	Yes
Participant information sheet	version 2.0	20/11/2022	20/12/2022	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes