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Can a clinical decision rule help ambulance paramedics identify older adults with a traumatic brain injury who would benefit from being transported to a hospital with onsite neurosurgical services?

Submission date
20/07/2021

Recruitment status
No longer recruiting

Registration date
29/07/2021

Overall study status
Completed

Last Edited
01/03/2023

Condition category
Injury, Occupational Diseases, Poisoning

[X] Prospectively registered
[_] 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 one of the leading causes of death and disability worldwide. Historically, it has been described as a disease of the young due to road traffic collisions, sporting injuries, falls from height and violence. However, older adults are becoming a prevalent patient demographic in TBI in high-income countries with ageing populations. This is due to falls from standing height, and the decline older adults experience through the natural process of ageing or long-term health conditions. Older adults who suffer a TBI are typically transported to the hospital by the ambulance service. A challenge facing ambulance paramedics is that these patients with TBI present with mild or no symptoms that reflect the severity of the underlying injury. This has resulted in most patients being transported to a hospital where neurosurgical services are not available onsite. This requires either remote consultation and/or a secondary transfer to a hospital where these services are available.
This study aims to develop a clinical decision rule that ambulance paramedics could use to help identify older adults (60 years or older) with a TBI and triage them to a hospital with neurosurgical services onsite.

Who can participate?
Patients aged 60 years or older with a TBI, suspected TBI or head injury, transported to hospital by the ambulance service

What does the study involve?
The study involves the linking of routinely collected data from ambulance and hospital patient care records. Clinical predictors (age, symptoms, mechanism of injury, etc) available to an ambulance paramedic at the scene of an injury are used to develop a prediction model. This

model is then evaluated to determine how accurate it would at identifying patients at the scene of the injury who would likely benefit from being transported to a hospital with neurosurgical services onsite.

What are the possible benefits and risks of participating?
The study is using routinely collected patient data so there will be no immediate benefit for these patients. However, the information generated from this study will help provide a better understanding of the care ambulance paramedics can provide to older adults suffering a TBI. In addition, all appropriate data security and protection standards have been met, and the study is compliant with GDPR. Therefore, there is minimal risk to the patient.

Where is the study run from?
South East Coast Ambulance Service and the University of Surrey (UK)

When is the study starting and how long is it expected to run for?
April 2020 to March 2023

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Jack Barrett
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Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
291682

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 291682

Study information

Scientific Title
Derivation and narrow validation of a clinical decision rule for paramedics to triage an older adult with a traumatic brain injury

Acronym
CEREBRAL

Study objectives
In patients 60 years or older with a traumatic brain injury, what are the risk factors that could accurately determine whether a paramedic should transport these patients directly to a major trauma centre for neurosurgical intervention?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 21/07/2021, East Midlands - Derby Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)207 1048310; derby.rec@hra.nhs.uk), REC ref: 21/EM/0103

Study design
Observational multi-centre cohort study using a retrospective linked dataset

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Traumatic brain injury

Interventions
There are five cohorts of patients to be screened during the study period:
1. Head CT positive for traumatic brain injury (TBI) referred and accepted by neurosurgeons: these patients will be transported to the ED of a hospital with neurosurgical services on site either as a primary transfer (closest hospital from the site of injury or a bypass) or a secondary transfer where they have been assessed, and treatment possibly commenced at another emergency department (ED). The neurosurgeon's online referral platform at South East Coast Ambulance Service NHS Foundation Trust (SECAmb) partner major trauma centres will be screened for eligible patients
2. Head CT positive for TBI referred, but not accepted, by neurosurgeons: these patients will be transported to a study ED with onsite neurosurgeons at SECAmb partner major trauma centres or another study ED where they have undergone a head CT scan, a TBI has been identified and been referred to neurosurgeons for review. However, patients were not accepted by the neurosurgeons, and another team managed their care. These patients will be recorded on the neurosurgeon's online referral platform. These patients will be screened for eligibility via this platform. Any follow-up data required and not available from the online platform will be requested from the patient's medical record.
3. Head CT negative for TBI: these patients will have entered a study ED via the ambulance service with a suspected TBI or apparent head injury and would have undergone a head CT scan, but their scan was negative for TBI. The ED database will be screened for eligible patients.
4. Head injury no CT scan: these patients will be transported to a study ED with a documented head injury in their ED or ambulance patient care record but not received a head CT scan. The ED and ambulance database will be screened for eligible patients.
5. Head injury not transported to hospital: these patients would have been seen by a SECAmb clinician and have a head injury documented on their ambulance patient care record. However, they would not have been transported to the hospital and either discharged at the scene or referred to another service. These patients will be screened via the ambulance record system

Groups 1 - 4 will have their hospital records linked to their respective ambulance record. Models will then be used to determine whether an ambulance paramedic should transport a patient to a hospital to a hospital with onsite neurosurgical services.

Intervention Type
Other

Primary outcome(s)
Patients accepted under neurosurgical services: identification of patients at the scene of their injury with a traumatic brain injury suitable for transportation to a hospital with onsite neurosurgical services through linking hospital and ambulance patient care records at a single timepoint

Key secondary outcome(s))
Collected from hospital and ambulance records at a single timepoint:
1. Patients with positive head CT scans for traumatic brain injury: identification of patients at the scene of their injury who would be suitable for transportation to the nearest hospital for a head

CT scan
2. Likelihood of transfer to neurosurgical services: the probability of a patient being admitted to a neurosurgical service based on the initial emergency department they were transported to
3. Unnecessary transportation to the emergency department for head CT scan following an injury: patients with a negative head CT scan following their incident who do not require any other services from the emergency department

Completion date
31/03/2023

Eligibility

Key inclusion criteria
1. Aged 60 years or older
2. Has a diagnosis of TBI; Traumatic Brain Injury; head injury, on the hospital admission form
3. Has a head injury recorded on their presenting reason or patient record crew condition code (C13 [Intracranial haemorrhage], M29 [Injury of the head (Disorder)]) on SECAmb patient care record
4. Has been seen, treated, transported, or discharged by a SECAmb clinician
5. Any severity of TBI

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
2868

Key exclusion criteria
1. Aged 59 and younger
2. Previous TBI
3. The patient presented to an ambulance service not participating in the study

Date of first enrolment
01/09/2021

Date of final enrolment
30/06/2022

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
South East Coast Ambulance Service
4 Nexus House
Gatwick Road
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RH10 9BG

Study participating centre
William Harvey Hospital
Kennington Rd
Willesborough
Ashford
United Kingdom
TN24 0LZ

Study participating centre
Queen Elizabeth The Queen Mother Hospital
St Peters Road
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CT9 4BG

Study participating centre
Kent and Canterbury Hospital
Ethelbert Road
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CT1 3NG

Study participating centre
Medway Maritime Hospital
Windmill Road
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ME7 5NY

Study participating centre
King's College Hospital
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SE5 9RS

Sponsor information

Organisation
South East Coast Ambulance Service NHS Foundation Trust

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

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?
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes