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Head Injury Transportation Straight to Neurosurgery (HITS-NS)

Submission date
02/02/2011

Recruitment status
No longer recruiting

Registration date
05/04/2011

Overall study status
Completed

Last Edited
25/05/2016

Condition category
Injury, Occupational Diseases, Poisoning

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Severe head injury is the most common cause of death and disability in people aged under 44 in the UK. Currently patients with severe head injury are transported by ambulance to the nearest hospital, regardless of whether that hospital has specialist brain surgeons (neurosurgeons). They are assessed by emergency doctors who then decide whether they need to be transported on to a specialist centre. This approach has the advantage of getting patients to a hospital quickly so they can be treated for any immediately life-threatening injuries, but has the disadvantage of increasing the time before they receive specialist care. An alternative approach is for patients with severe head injuries and no other obvious life-threatening injuries to bypass the nearest hospital and go straight to a specialist neurosurgical centre. This has the advantage of getting the patient to specialist care quicker, but may delay treatment of other serious injuries. For example, a patient with serious internal bleeding that is not recognised by the paramedics could have treatment of this bleeding delayed if they bypassed the nearest hospital and were taken to a specialist centre. This issue has recently been debated in the national media and patients with serious head injuries have been used as an example where travelling a longer distance to a specialist hospital could be in the patients' interest. However, the National Institute for Health and Clinical Excellence (NICE) recently decided that the current evidence was inconclusive, and stated that this is an important issue in need of further study. We plan to answer this question by undertaking a feasibility study for a larger study, in which patients will be randomly allocated to either be transferred to the nearest hospital or transferred directly to a specialist neurosurgical centre.

Who can participate?
Patients aged over 15 with a severe head injury

What does the study involve?
Participating ambulance stations are randomly allocated to either transport all head injury patients straight to a specialist neurosurgical centre, or to the nearest hospital (usual care). We assess whether ambulance service crews comply with the random allocation and recruit the right patients. We also measure patients' survival and health over the following six months to detect if either approach leads to better outcomes for patients. We also calculate whether bypassing the nearest hospital is cost effective.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Salford Royal Hospital (UK)

When is the study starting and how long is it expected to run for?
July 2011 to June 2012

Who is funding the study?
NIHR Health Technology Assessment Programme - HTA (UK)

Who is the main contact?
Dr Fiona Lecky

Contact information

Type(s)
Scientific

Contact name
Dr Fiona Lecky

Contact details
Trauma Audit and Research Network
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Salford Royal Hospital
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Additional identifiers

Protocol serial number
2010v1; HTA 08/116/85

Study information

Scientific Title
Head Injury Transportation Straight to Neurosurgery (HITS-NS): a cluster randomised feasibility study

Acronym
HITS-NS

Study objectives
HITS-NS will:
1. Determine the feasibility of conducting a cluster randomised trial of early neurosurgery in patients with traumatic brain injury

2. Determine the acceptability of the intervention (early neurosurgery) and control (usual care) pathways to patients, families and staff
3. Estimate the "magnitude of effect" of early neurosurgery and other parameters required for sample size estimation, thus enabling costing of a full study (given successful recruitment)
4. Determine the accuracy with which paramedics identify isolated traumatic brain injury at the incident scene (given successful recruitment)
5. Estimate the cost per quality-adjusted life year (QALY) of early neurosurgery, compared with usual care, based on currently available data (including data from this pilot) and the degree of uncertainty surrounding this estimate
6. Determine the Expected Value of Sample Information (EVSI) from a fully powered cluster randomised trial of early neurosurgery in patients with traumatic brain injury
7. Identify the major barriers to conducting a cluster randomised trial of early neurosurgery in patients with traumatic brain injury and the strategies to overcome them
8. Contribute to the existing evidence about conducting randomised trials in pre-hospital care through identifying barriers and facilitators of successful strategies that are generic to pre-hospital trials

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/0811685
Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0014/52061/PRO-08-116-85.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
West North Wales Ethics Committee, October 2010, ref: 10/WNO03/30

Study design
Cluster randomised feasibility study

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Time:
HITS-NS is not studying a new patient intervention, the new technology under scrutiny is the timing of neurosurgery in patients who are injured nearest an acute hospital emergency department, versus the time to any interventions that may be required to stabilise the injured patient's airway breathing and circulation. Time zero will be the time that paramedic leaves the scene of the incident with the injured patient.

Neurosurgery:
Neurosurgery includes any of craniotomy for evacuation of intracranial haematoma, debridement of open fractures, and insertion of ICP monitor. Time to neurosurgery will be from time zero to the time that the patient is anaesthetized for whichever of these procedures comes

first. It is envisaged that this will occur early (within 4 hours of time zero) in the intervention group. The trial management group will ensure that Neurosurgical centres will be able to suspend the intervention arm of the trial in their respective areas at short notice should HITS-NS appear to be placing unsustainable demands on their resources.

ABC stabilisation:
The interventions that stabilise the injured patients' airway, breathing and circulation that fall outside the scope of paramedic practice include endotracheal intubation facilitated by drugs (ETI), decompression of tension pneumothorax (if present) and surgery/ interventional radiology to control internal haemorrhage as dictated by the patient's injuries and physiological status. Most HITS-NS patients will require ETI; the other interventions will be less frequent. The time to each of these interventions will be recorded, the time to ABC stabilisation will be from time zero to whichever ABC intervention procedure is first commenced. It is likely, but not necessarily a given that this will occur up to 30 minutes earlier in the control (usual care) group. Paramedics will be trained to exclude patients with signs of imminently requiring these interventions from the study.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
1. The actual versus required recruitment rate to HITS NS for each ambulance service (AS). For the study to be considered feasible the monthly recruitment rate should be at least 50% of that required and increasing at 12 months. The recruitment rate should also be equivalent within control and intervention clusters within each AS. Recruitment will depend on early patient identification by the research paramedics from patient report forms then later obtaining patient / next of kin consent to follow up. The required rate is determined by the power calculation and current incident rate of TBI presenting to each AS.
2. The degree of selection bias caused by non - compliance with HITS-NS randomisation for each AS. For further study to be considered feasible there should be no significant difference between the characteristics of patients in groups where randomisation is and is not complied with. This should be true overall and within each trial arm. These characteristics include absolute patient transportation times from the nearest AHED and neurosurgical hospitals, and the increase in transportation time involved in bypassing nearest AHED. There should also be equivalence of factors determining survival and disability after TBI including age, Injury Severity Score (ISS), scene vital signs, pupillary responses and severity of TBI.
3. Rate of compliance with trial randomisation for each AS. For further study to be considered feasible the non compliance rate should not exceed 10% (in each arm)
4. Rates of acceptability of control and intervention pathways to patients, staff and families. For a full trial to be feasible there should be no significant difference between trial arms. This will be assessed by questionnaires and incident reporting.
5. Rates of actual TBI in patients recruited to the trial. For further study to be considered feasible this should exceed 80% in each AS and be equivalent between trial arms.

Key secondary outcome(s))
1. Six-month Extended Glasgow Outcome Scale
2. EQ-5D scores
3. 30-day mortality

Completion date
30/06/2012

Eligibility

Key inclusion criteria
Patients injured nearest an acute general hospital Emergency Department (AHED) but not more than one hour land ambulance journey from a neuroscience centre (NC) thought to be aged greater than 15 years, when assessed at scene by ambulance personnel with both:
1. Signs of significant TBI such as a reduced conscious level (GCS less than 13) and external signs of head injury, and
2. No overt signs of airway, breathing and circulation compromise

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Patients who fulfil ANY of the following criteria will be excluded:
1. Thought to be aged less than 16 years
2. Have been found by the treating paramedic to not have signs of traumatic brain injury at the scene (i.e. full or only mildly impaired consciousness GCS greater than 12)
3. Who have obvious life threatening injuries affecting the airway, breathing or circulation:
A. Partial or complete airway obstruction/contamination present after simple manoeuvres
B. Respiratory rate less than 12 or greater than 30, or sucking chest wound or signs of tension pneumothorax such as absent air entry into a hemithorax with contralateral tracheal deviation
C. Significant external haemorrhage not easily controlled by pressure, or amputation above the wrist or ankle or absence of radial pulse on palpation
(Paramedics recognise these signs as part of their current scope of practice)
4. Who are injured more than an hour's travelling time from a neuroscience centre

Date of first enrolment
01/07/2011

Date of final enrolment
30/06/2012

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Salford Royal Hospital
Eccles Old Road
United Kingdom
M6 8HD

Sponsor information

Organisation
University of Manchester (UK)

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2015		Yes	No
Results article	results	01/01/2016		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes