Appendix 6

HITS-NS STUDY NEAS/NWAS PROTOCOLS v5/v6[1]

AIM: To improve care for patients with traumatic brain injury

Research 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, in NWAS paramedics, and in NEAS both paramedics and Level 2 Emergency Medical Technicians, 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.

Inclusion Criteria: Patients injured nearest an acute general hospital Emergency Department (NSAH) but not more than one hour land ambulance journey from a neuroscience centre (SNC) thought to be aged > 15yrs, when assessed at scene by ambulance personnel with both

In NWAS:

i) Signs of significant TBI such as a reduced conscious level (GCS < 13) and external signs of head injury AND
ii) No overt signs of airway, breathing and circulation compromise.

In NEAS:

i) Signs of significant TBI such as a reduced conscious level (GCS < 14) and external signs of head injury AND
ii) No overt signs of airway, breathing and circulation compromise.

Exclusion criteria: Patients who fulfil ANY of the following criteria will be excluded:

i) thought to be aged <16 years
ii) who have been found by the treating paramedic in NWAS, or by the treating paramedic / Level 2 Emergency Medical Technician in NEAS, to not have signs of traumatic brain injury at the scene (i.e. full or only mildly impaired consciousness GCS > 12 in NWAS; or full or only mildly impaired consciousness GCS > 13 in NEAS)
iii) Who have obvious life threatening injuries affecting the airway, breathing or circulation:

A - Partial or complete airway obstruction / contamination present after simple manoeuvres, or any patient who has been intubated or had a supraglottic device inserted at the scene of injury

[1] This merged protocol shows the differences between the two REC approved working protocols for NWAS (v6) and NEAS (v5) respectively. These differences apply solely to the inclusion and exclusion criteria. The differences have arisen due to the variations in the Major Trauma Bypass Protocols which became operational in NWAS and in NEAS during the conduct of HITS-NS.

B - Respiratory rate < 10 or > 30 in NWAS, or Respiratory rate < 12 or > 30 in NEAS, 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)

iv) Who are injured more than an hour's travelling time from a neuroscience centre.

Retrospective exclusion criteria
Any surviving patient where consent has not been given by either the Ambulance Service Mental Capacity Act Consultee, patient or relative for follow up

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Recruitment: The unit of cluster for the trial is the ambulance station (AS) of which there are 30 within each of the ambulance services (60 in total). 30 AS will be intervention stations and will take patients meeting the inclusion criteria (past the nearest Emergency Department) straight to the nearest neuroscience centre for the duration of the trial. The 30 control AS will practice usual care by taking patients to the nearest Emergency Department. Patient identification will be confirmed by the research paramedics the following day. Patients will be formally recruited and consented during their hospital stay as described below.

The HITS-NS participants will lack capacity as a result of traumatic brain injury (TBI); the study seeks to improve care for TBI patients.

HITS-NS falls within the remit of the Mental Capacity Act 2005 (Section 30-32) as it seeks to randomise adults who lack capacity as a result of traumatic brain injury.

(HITS-NS is not a trial of a new interventional or medicinal product (CTIMP); early neurosurgery already occurs in patients injured nearest to a neuroscience centre therefore it does not fall under the jurisdiction of the MHRA).

We have considered carefully the requirements of the MCA. There will be no time at the scene to ask a personal consultee (if available), independent medical practitioner or ambulance service consultee for advice about including the patient. We therefore seek permission to obtain consent for inclusion of data in hospital after the patient has been allocated to the control or intervention pathway. We appreciate that at this stage consent is for inclusion of data and for follow up and hope the REC will see this as acceptable as at present there is equipoise between the control and the intervention pathways.

Prior to commencement of the study in the trial areas HITS-NS trial monies will pay for a PR firm to publicise the trial in the local media to allow local communities to be aware of the trial and debate and discuss its merits with the investigators.

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 arrives in theatre 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.

Consent: The research paramedic will identify the trial patients through the daily PRF search and contact staff caring for the patient in the respective hospital. The research paramedic will request that they (the staff) approach the HITS-NS participant (if they have recovered capacity) or suitable personal consultee - at an appropriate time - to ask if they are happy to speak to a researcher, and for a suitable time. Only patients or relatives who are happy to speak to a researcher will then be seen on the ward by the research paramedic who will provide them with the HITS-NS patients/consultees information sheet prior to requesting consent or advice.

We request REC permission not to approach families of participants who die within a week of reaching hospital but to include anonimised data within the study database.

Patients or designated personal consultees who agree to be approached by a researcher will be approached by the HITS-NS research paramedic for the ambulance service. These will be current senior paramedics seconded into this role using trial monies (to be released after REC approval hence we cannot give specific identities as yet). The research paramedic will provide patients or the consultee with an explanation of the purpose of the study and what it entails. They will be given the study information sheet and allowed as much time to consider it as needed with the limit of a decision before discharge from the acute hospital. If the patient or consultee is agreeable they will sign accordingly and their data (age, injuries, timing of interventions) will be accessed from their care records and uploaded (anonymised) onto the study database.

Occasionally patients who appear to have significant TBI at scene may for example be intoxicated with no significant injuries, and be discharged from hospital the next morning before they can be approached by the research paramedic. In this situation, in order to allow a full intention to treat trial evaluation, we request permission to obtain the patient's address and telephone number from hospital records and post a patient information sheet and a letter requesting that the patient agrees to be telephoned to discuss whether they wish to participate in HITS-NS. There will be a tear off slip to post back saying that they are willing to be approached. If the slip is not received back within two weeks of sending then the research paramedic will send patients with a recorded mobile phone number (on the patient record) a text message requesting permission to telephone the patient and discuss the study. If a slip or text message prior to when follow-up would be scheduled to take place is received, the patient will be telephoned by the research paramedic, further information will be supplied and consent for inclusion of data and follow up will be taken over the telephone when the patient has had time to consider the request. If the slip or txt message is not returned no further contact will be made with the patient, however we will record anonymised patient injury details and 30 day outcome on the trial database.

There will be no further contact with the participant or consultee until 6 months after injury when the telephone (GOSE) and questionnaire follow up will take place.

Results The main aim of this feasibility study is to determine whether or not there is sufficient recruitment and paramedic compliance with the cluster allocation to enable a full study.

The patient outcomes (30 day mortality, 6 month GOSE) will be monitored by an independent data monitoring committee however this pilot study with 12 months recruitment is unlikely to recruit

more than 750 patients and is extremely unlikely to show a patient outcome difference between either pathway.

We will bid for HTA for sufficient funding for a full trial across 4 ambulance services Recruiting 4,100 patients if all the four following conditions are met

a. Equipoise is maintained
b. There are no serious adverse incidents or major trial objections
c. The recruitment rate is 50% of that required in both ambulance services and rising
d. There is 90% compliance with allocation by paramedics within both arms of the trial.

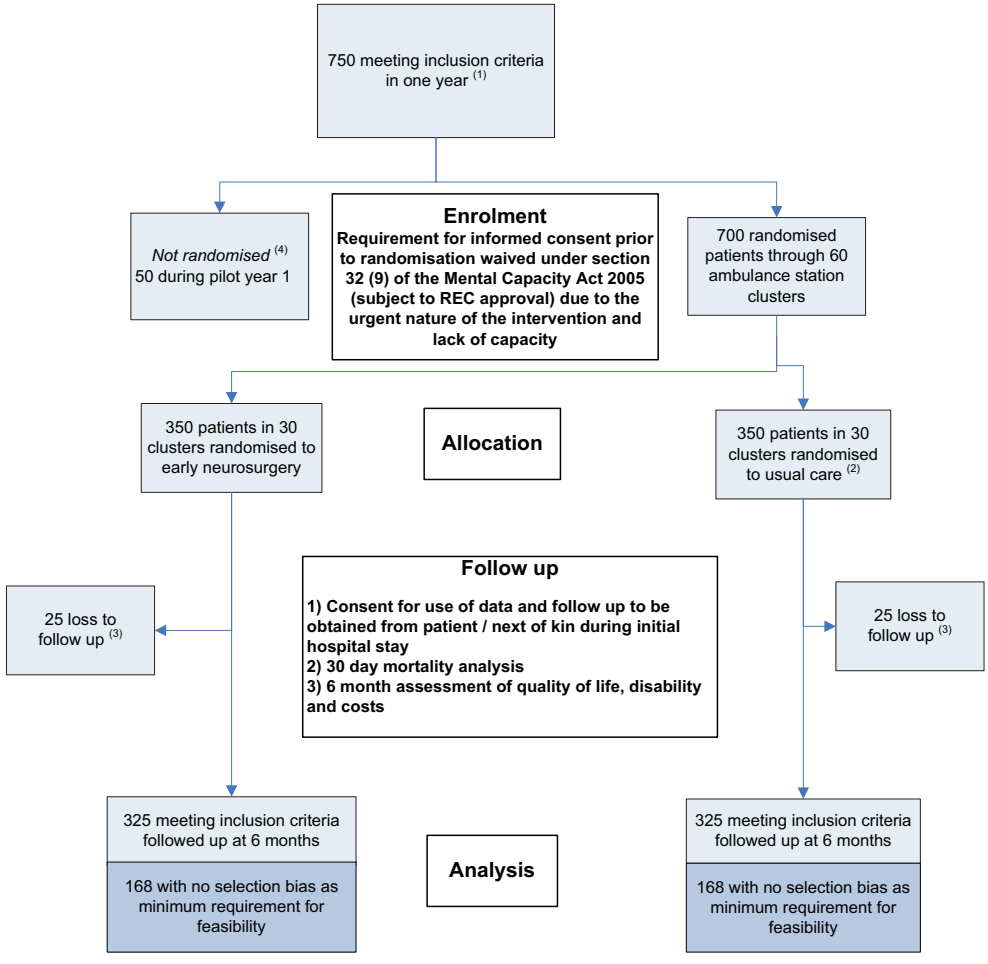
Dissemination

The final report to HTA will present detailed results of the feasibility study, and make recommendations whether / how full HITS-NS should proceed. From this basis it will be possible to identify the barriers to conducting HITS-NS (e.g. recruitment, compliance, a lack of uncertainty), and successful strategies to address these where applicable. From this there will be generic lessons to allow recommendations on the conduct of future pre-hospital trials to be made. The ongoing progress of the pilot will be disseminated to paramedics through newsletters and regional meetings, to the trauma community through relevant professional newsletters, national and international conferences, and to patients via Headway, TARN and ScHARR websites. HITS-NS papers will be submitted to relevant professional and high impact peer-reviewed scientific journals. The findings of HITS-NS will also be reported to the newly appointed National Clinical Director for Trauma Care and SHA's to help guide the development of regional trauma networks in the wake of the Darzi review.

20 July 2012

Version 6

Head Injury Transportation Straight to Neurosurgery (HITS – NS) - a feasibility study



(1) Ambulance Service data suggests that annually at least 1500 patients with GCS < 13 who would not get early neurosurgery are injured nearest to AHEDs in the trial areas (see table)

(2) Usual care is resuscitation and CT brain at general hospital followed by transfer to neurosurgical hospital within 24 hours

(3) This may seem a high loss to follow up rate – we will strive to minimise this recurrent issue in TBI trials

(4) Pragmatic acceptance of realities of making this trial work in the acute situation: the trial may not be acknowledged and enrolment not occur in these cases – these patients will be studied for injury, demographic and outcome characteristics through health records to ensure no selection bias

Project Reference: Lecky 08/116/85

TRIAL NEURO CENTRE	TRIAL ACUTE HOSPITALS	AMBULANCE SERVICE
Royal Preston Hospital	Blackburn Royal Infirmary	NWAS
	Blackpool Victoria Hospital	
	Royal Lancaster Infirmary	
Royal Victoria Infirmary	North Tyneside General Hospital	NEAS
	Queen Elizabeth Hospital (Gateshead)	
	South Tyneside District Hospital	
	Sunderland Royal Hospital	
	Wansbeck General Hospital	
James Cook University Hospital (Middlesborough)		NEAS
	University Hospital of North Durham	
	Darlington Memorial Hospital	
	University Hospital of North Tees	