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The Head Injury Transportation Straight to Neurosurgery (HITS-NS) randomised trial: a feasibility study

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Plain English summary

The HITS-NS randomised trial: a feasibility study

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Plain English summary

Severe head injury is the most common cause of death and disability in people aged < 44 years in the UK. When we were funded to conduct this study (and up until April 2012 outside London) patients with suspected severe head injury were transported by ambulance to the nearest hospital, regardless of whether or not that hospital had specialist brain surgeons (neurosurgeons). They were assessed by emergency doctors who decided whether or not they needed to be transferred on to a specialist centre. This approach has the advantage of getting patients to a hospital quickly so that 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 suspected severe head injuries and no other obvious life-threatening injuries to bypass the nearest hospital and go straight to a specialist neurosurgical centre. Since April 2012 this has been standard practice in the NHS in England. It 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. In addition, it is not always easy to definitively diagnose whether or not an unconscious patient at the incident scene definitely does have a severe head injury, as impaired consciousness can be caused by many other factors.

The National Institute for Health and Care Excellence recently decided that current evidence for bypassing the nearest hospital in favour of a specialist centre was inconclusive, and stated that this is an important issue in need of further study.

We attempted to answer the question of which approach is superior by undertaking a feasibility study for a randomised trial, in which patients were either transported to the nearest hospital or transported directly to a specialist neurosurgical centre. We needed to see whether or not ambulance service (AS) crews would comply with the randomisation and recruit the right patients before designing a full trial. We also measured patients' survival and health over the following 6 months to detect if either approach leads to better outcomes for patients during the feasibility study.

We also used the pilot data to create a best estimate as to whether or not bypassing the nearest hospital is cost-effective. We used complex statistical modelling for this to reflect the multitude of influences on patient outcome and, where possible, supplemented the pilot data with literature reviews and information from experts concerning head injury patients currently receiving usual care in order to make the estimate as precise as possible. We carried out this feasibility study over 2 years in two regional ASs covering three specialist centres and 11 general hospitals. An independent ethics committee approved our research plans and there was continuing independent oversight from clinicians, researchers and Headway to ensure that the interests of patients remained paramount throughout.

These two work streams have enabled us to decide that the bypass trial is feasible in a practical sense, as the randomised trial within ASs worked well, especially when face-to-face paramedic training was possible. This is a promising finding for future research. However, the study showed that fewer than one-quarter of patients with suspected severe head injury at the scene turned out to have one on their brain scan, making the effect of any 'early neurosurgery' very diluted in this patient group – only 20 out of 293 patients required any brain surgery. A further trial to show the effect of early brain surgery would be unfeasibly large. The majority of patients recruited had minor injuries and had short periods of unconsciousness that resolved after < 24 hours in hospital and before they could be visited by trial staff for consent. We were able to record anonymised 30-day survival in 93% of enrolled patients, but the vast majority of patients with minor injuries did not respond to written invitations for consent to follow-up. This is consistent with other studies in this 'mild head injury' cohort. We are confident from our checks on screening that we did not miss many eligible patients (fewer than five).

There were no differences in the patient characteristics of those recruited into both arms of the trial or in the 30-day death rates (9% in both arms). When we were able to conduct studies of patient satisfaction at 6 months post injury, there were no differences between either trial arm (generally high levels of satisfaction with care) and paramedics were positive about the study in the focus groups and feedback.

Given the low rates of brain surgery in the study, the extensive statistical modelling of cost-effectiveness was uncertain as to the value of bypass in this patient group. Because of the public health importance of severe head injury, a further trial of 'bypass' as a health technology, rather than 'early brain surgery', may represent value for money for the NHS. However, there are logistical issues in delivering this among the new trauma systems. The difficulties of consent/following up patients with relatively minor head injuries are considerable, and perhaps insurmountable, challenges.

It may now be possible to 'observe' the effects of bypass on early mortality across NHS England using national trauma audit while controlling for other influences. Our screening checks and some recent publications indicate that a significant proportion of patients who go on to require brain surgery for head injuries have full or almost full consciousness at the scene of injury, and are hence not 'eligible for bypass'. Secondary transfer from the nearest hospital to specialist centres will continue to be an important pathway for this group of patients.

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