



Surgical Trial in Traumatic intraCerebral Haemorrhage STITCH(Trauma)

Intracranial haemorrhage occurs in more than 60% of head injuries in one of 3 types: extradural (EDH), subdural (SDH) and intraparenchymal (TICH). Prompt surgical removal of significant SDH and EDH is of established and widely accepted value. However, TICH is more common and is found in more than 40% of severe head injuries. It is clearly associated with a worse outcome but the role for surgical removal remains undefined.

Surgical practice in the treatment of TICH's differs widely around the world. The main aim of early surgery TICH removal is to prevent secondary brain injury. There have been trials of surgery for spontaneous ICH (including the ongoing MRC funded STICH II trial, but none so far of surgery for TICH.

The UK National Institutes of Health Research has provided funding for the STITCH(Trauma) study to determine whether a policy of early surgery in patients with TICH improves outcome compared to a policy of initial conservative treatment. It will include a health economics component and will carry out a subgroup analysis of patients undergoing invasive monitoring. The study will be undertaken alongside STICH II. This is an international multicentre pragmatic randomised controlled trial.

Eligible patients will be:

- within 48 hours of injury
- have evidence of a TICH on CT scan with a confluent volume of attenuation significantly raised above that of the background white and grey matter that has a total volume greater than 10mls calculated by (width x height x length)/2 in cm
- treating neurosurgeon should be in equipoise.

Patients will be ineligible if they have:

- A significant surface haematoma (EDH or SDH) requiring surgery
- If the haemorrhage/contusion is located in the cerebellum.
- 3 or more separate haematomas fulfilling inclusion criteria
- severe pre-existing physical or mental disability or severe co-morbidity which would lead to poor outcome even if the patient made a full recovery from the head injury.

Patients will be randomised via an independent telephone or web randomisation service. Patients randomised to surgery will receive surgery within 12 hours. Both groups will be monitored according to standard neurosurgical practice. All patients will also have a CT scan at about five days (+/- 2 days) to assess changes in the haematoma size. Patients will be followed up by postal questionnaire at 6 months and 12 months. In total 840 patients will be recruited to the study between October 2009 and March 2013.

For further information email: **trauma.stitch@ncl.ac.uk**

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