

Surgical Trial in Traumatic Intracerebral Haemorrhage

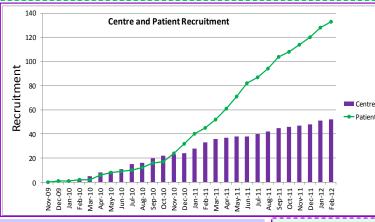
Newcastle University

New STITCH (Trauma) Randomisation Service Telephone Number: +44 (0) 1224 273 661 Web randomisation details remain unchanged.

Congratulations to University Hospital Marquès de Valdecilla (Santander, Spain) who have recruited their first patient and All India Institute of Medical Sciences (New Delhi, India) who have recruited 6 patients since our last newsletter.

A big thank you also to CSM Medical University (Lucknow, India), Beijing Tiantan Hospital (China), Neuro Hospital (Biratnagar, Nepal), Huashan Hospital (Shanghai, China), University Hospital Heidelberg (Germany) and Himalayan Institute of Medical Sciences (Dehradun, India) who have all recruited since our winter newsletter to help us reach

134 patients!



There are now

52 registered centres in the trial
and 50% have recruited at least
one patient.

So far in 2012, a total of 14 patients have been recruited by 6 centres.

We appreciate the efforts of all our collaborators and hope all registered centres are able to find suitable patients in 2012!

Inclusion Criteria

Evidence of 1 or 2 TICHs or contusions 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).

Clinical equipoise; only patients for whom the responsible neurosurgeon is uncer-

Exclusion Criteria

Severe pre-existing physical or mental disability or severe co-morbidity which would lead to a poor outcome even if the patient made a full recovery from the head injury.

tain about the benefits of either treatment are eligible

A significant surface haematoma (EDH or SDH) requiring surgery

Permanent residence outside a study country preventing follow up

· Patient and/or relative has a strong preference for one treatment modality

Three or more separate haematomas fulfilling inclusion criteria.
 If surgery cannot be performed within 12 hours of randomisation

. If the haemorrhage/ contusion is located in the cerebellum

· Adults aged 14 or over

Welcome to our new centres!

Those who have joined the study since our last newsletter are highlighted below in purple.

| Centre | Total | Change |
|-----------------------|----------|------------|
| | Patients | since last |
| Lucknow | 26 | 2 |
| Beijing | 24 | 4 |
| Biratnagar | 15 | 1 |
| Dehradun | 13 | 1 |
| Visakhapatnam | 7 | 0 |
| New Delhi | 6 | 6 |
| Shanghai | 6 | 1 |
| Timisoara | 5 | 0 |
| Tianjin | 4 | 0 |
| Ludhiana | 3 | 0 |
| Newcastle | 3 | 0 |
| Wardha | 3 | 0 |
| Dundee | 2 | 0 |
| Heidelberg | 2 | 1 |
| Kaunas | 2 | 0 |
| | 2 | 0 |
| Mysore | 2 | 0 |
| Peshawar | | |
| Bangalore | 1 | 0 |
| Brno | 1 | 0 |
| Chennai | 1 | 0 |
| Cluj | 1 | 0 |
| Haryana | 1 | 0 |
| Munich | 1 | 0 |
| Santander | 1 | 1 |
| Southampton | 1 | 0 |
| Valladolid | 1 | 0 |
| Alexandria | 0 | 0 |
| Calcutta | 0 | 0 |
| Haywards Heath | 0 | 0 |
| Hyderabad | 0 | 0 |
| Jena | 0 | 0 |
| Johor Bahru | 0 | 0 |
| Kerala | 0 | 0 |
| Klaipeda | 0 | 0 |
| Kubang Kerian | 0 | 0 |
| Leeds | 0 | 0 |
| London (Queen Square) | 0 | 0 |
| London (St Georges) | 0 | 0 |
| Louisville | 0 | 0 |
| New York | 0 | 0 |
| Pennsylvania | 0 | 0 |
| Philadelphia | 0 | 0 |
| Portland | 0 | 0 |
| Riga | 0 | 0 |
| Rome | 0 | 0 |
| Szeged | 0 | 0 |
| Toronto | 0 | 0 |
| Hlm | 0 | 0 |
| | | |

Ulm-Günzburg

Yerevan

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Good Clinical Practice (GCP) Tips

Here are some tips to help you run your STITCH(Trauma) site smoothly:

- Make copies of all signed consent forms give one to the patient/relative, keep one for your local STITCH(Trauma) records and place one in the patient's medical notes.
- Ensure all patients/relatives are given copies of trial information sheets to take home in case they have questions later.
- File copies of the signed consent form, randomisation form, two week form, any adverse event forms and any correspondence concerning the patient's involvement in the trial or their trial data in the Site Masterfile and keep it in a secure place where only study staff have access.
- Ensure that all the staff assisting you with the trial have easy access to the relevant trial documentation and forms.
- If a STITCH(Trauma) patient suffers a major adverse event please report this as soon as possible by faxing a completed major event form to +44 (0) 191 222 5762.

The team have just published the following article:
Traumatic Intracerebral Haemorrhage –To Operate or Not?
World Neurosurgery 2012 76[6]: 484-485

This map shows the number of visits to the STITCH (Trauma) website by cities around the world since 1st January 2012.

As you can see, a large number of visits are from Europe (in particular the UK),

North America and India.

Please visit:

http://research.ncl.ac.uk/ trauma.STITCH/

For up to date information, presentations and copies of all our newsletters.



The STITCH (Trauma) team will be at the following meetings:

Ninth World Congress on Brain Injury, Edinburgh, UK; 21st-25th March 2012 SBNS, Aberdeen, UK; 18-20th April 2012 AANS, Miami, USA; 14-18th April 2012 EMN, Cluj, Romania; 27-28th April 2012

ICRAN, Novosibirsk, Russia; 19th-22nd June 2012

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