

STITCH (Trauma) **NEWSLETTER**



Surgical Trial in Traumatic Intracerebral Haemorrhage

Summer 2010

Issue 3

Centres who are able to recruit patients:

Beijing Tiantin Hospital
Tianjin Medical University General Hospital

Czech Republic:

University Hospital Brno

BGS Global Hospital, Bangalore Care Hospital, Visakhapatnam Christian Medical College & Hospital, Ludhiana CSM Medical University, Lucknow Himalayan Institute of Medical Sciences, Dehradun Kerala Institute of Medical Sciences, Kerala

Acharva Vinoba Bhave Rural Hospital, Maharashtra

Lithuania:

Klaipeda Hospital

University Hospital Marquès de Valdecilla,

Santander

Newcastle General Hospital Ninewell's Hospital, Dundee Southampton General Hospital

Centres who have expressed an interest in the trial:

Armenia: Yerevan Austria: Graz Brazil: Santa Paulo Canada: Toronto China: Hong Kong Croatia: Osijek Cuba: Ciego de Avila Czech Republic: Budweiss Egypt: Mansoura, Zagazig

Estonia: Tallinn

France: Guadeloupe, Paris

Germany: Amberg, Kassel, Hamburg, Magdeburg, Munich, Solingen, Ulm

Greece: Athens, Chania Hungary: Borsod, Pecs, Szeged

India: New Delhi, Calcutta, Chennai, Dehradun, Hyderabad, Kochi, Mysore, New Delhi, Noida

Israel: Rambam, Tel-Aviv

Italy: Rome Latvia: Riga Lithuania: Kaunas Macedonia: Skopje Malaysia: Kuban Kerian Nepal: Biratnagar Poland: Warsaw

Romania: Clui-Napoca, Timisoara

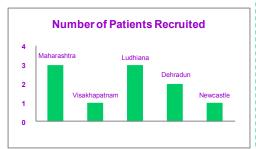
Russia: Chelyabinsk Saudi Arabia: Madina UK: Brighton, London Ukraine: Uzhgorod, Vinnitsa

USA: Albany, New York, Pennsylvania, Philadelphia

10 patients now recruited!

Congratulations to Christian Medical College & Hospital, Ludhiana, India for recruiting our 10th STITCH (Trauma) patient on 19th July 2010. We are also delighted to announce that we now have 15 fully registered centres who are able to recruit patients including our 2 new sites, Tianjin Medical University General Hospital, China and BGS Global Hospital, Bangalore, India.

In addition to the centres who are fully registered, we have another 14 sites who are in the process of completing regulatory processes who will be joining us shortly.



How to Randomise Patients

For those of you who are new to the trial, here are the steps you need to follow in order to randomise a patient:

- 1. Check the patient meets the inclusion criteria
- 2. Give the patient and/ or relative information about the trial (verbally and by printed information sheets)
- 3. Take consent from the patient or next of kin
- 4. Complete a paper randomisation form
- 5. Telephone our randomisation service on +44 (0) 1224 551 261

News

We would like to notify you that Helen Atkinson (our trial administrator) has been promoted to a new job in Newcastle University. We would therefore like to thank Helen for all her hard work and wish her all the best for the future!

We are delighted to welcome Courtenay Howe who has joined the trial team to replace Helen. Please do not hesitate to contact Courtenay by emailing trauma.stitch@ncl.ac.uk if you need any further assistance!

STITCH (Trauma) Inclusion and Exclusion Criteria

Inclusion Criteria

- Adults aged 14 or over.
- Evidence of 1 or 2 TICHs or contusions with a confluent volume of attenuation significantly raised above that of the background white and grev matter that has a total volume greater than 10mls (calculated by width x height x length /2 in
- Within 24 hours of head injury.
- Clinical equipoise: only patients for whom the responsible neurosurgeon is uncertain about the benefits of either treatment are eligible.

Exclusion Criteria

- A significant surface haematoma (EDH or SDH) requiring surgery.
- Three or more separate haematomas fulfilling inclusion criteria.
- If surgery cannot be performed within 12 hours of randomisation.
- 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.
- Permanent residence outside a study country preventing follow up.
- Patient and/or relative has a strong preference for one treatment modality.

National Ethical Approval obtained for Germany!

We are delighted to announce that Professor Andreas Unterberg, our German National Coordinator for STITCH (Trauma) has obtained ethical approval for Germany! This should make it easier for German sites wishing to participate to gain local ethical approval. Please do not hesitate to contact the STITCH (Trauma) team if you require any further assistance.

Telephone: +44 (0) 191 28 21113 Fax: +44 (0) 191 28 21118

Email: trauma.stitch@ncl.ac.uk Website: www.ncl.ac.uk/trauma.stitch