



STITCH (Trauma) NEWSLETTER



Surgical Trial in Traumatic Intracerebral Haemorrhage

Winter 2010

Issue 4

How to Randomise STITCH(Trauma) 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. Contact our randomisation services on +44 (0) 1224 551 261 or : <https://viis.abdn.ac.uk/HSRU/stitch/>

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 grey matter that has a total volume greater than 10mls (calculated by width x height x length / 2 in cm).
- 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.

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. Please also fax/post a copy to the STITCH(Trauma) office.
- Ensure all patients/relatives are given copies of trial information sheets to take home in case they have questions later.
- File your STITCH(Trauma) data/patient records securely in a centralised 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.

27 patients now recruited!

Seasons Greetings!

Congratulations to all sites who have recruited STITCH(Trauma) patients so far!

We have now **achieved our second pilot phase target** of 24 patients!

In order to achieve our final target we will need **more sites** to join us. If you have not already registered your hospital as a recruiting centre please send in your completed site questionnaire as soon as possible so that we can get the process started.

Site questionnaires and more information can be obtained at our website:

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

News

A lot has happened since our last quarterly newsletter!

We have now **moved** to new offices and our new address is:

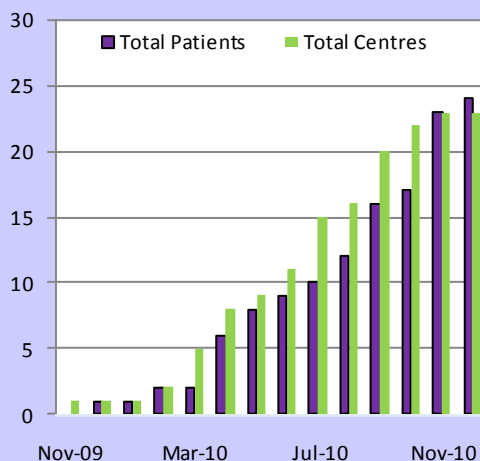
**Neurosurgical Trials Unit, 3-4 Claremont Terrace, Newcastle University,
Newcastle upon Tyne, NE2 4AE, UK.**

If you are already participating in the trial please be sure to incorporate these new contact details into your local consent forms and information sheets.

We are also delighted to welcome our new data manager **Dr Richard Francis** to the team!

Richard has given the **STITCH(Trauma) website** a trendy new look so please take a glance at it and catch up with the latest trial information at <http://research.ncl.ac.uk/trauma.STITCH/>

Trial Recruitment



Current recruiting centres

UK:

Newcastle (3)
Southampton General Hospital (1)
Ninewell's Hospital, Dundee (1)
Haywards Heath (0)

Europe:

Klaipeda Hospital (0)
University Hospital Brno (1)
University Hospital Marqués de Valdecilla (0)
County Hospital, Timisoara (0)
University of Szeged (0)
University Hospital Heidelberg (0)

Rest of the World:

Rural Hospital, Maharashtra (3)
Care Hospital, Visakhapatnam (3)
Christian Medical College, Ludhiana (3)
Himalayan Institute, Dehradun (5)
Beijing Tiantan Hospital (0)
Kerala Institute of Medical Sciences (0)
CSM Medical University, Lucknow (7)
BGS Global Hospital, Bangalore (0)
Tianjin Medical University (0)
Mysore Clinisearch, Nazabad (0)
Zagazig University Hospital (0)
Neuro Hospital, Biratnagar (0)
Albany Medical College (0)

Investigators Meeting

Our first Investigators meeting is in Newcastle, UK on 2nd May 2011 during the joint EANS Annual meeting-4th World ICH Conference.

The deadline for submitting abstracts is 2 February 2011.

Further information about the conference can be obtained from the conference website:

<http://www2.kenes.com/eans-ich/Pages/Home.aspx>

We hope to see as many of you as possible there and will send out more details in the New Year!



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