EDITORIAL
Professor Richard Lindley, Co-Chief Investigator

IST-3 Recruitment Accelerates – Best Ever Month!

Our New Year goal was to pass 1425 patients recruited by the end of January and we have easily achieved this with a recruitment of 1441 today (26th January), with our best ever rate of 49 patients in the past 30 days. Congratulations to all those centres who successfully recruited during and around the holiday season. We hope we can build on this recruitment rate over the coming year.

IST-3 was the first stroke RCT to incorporate consumer involvement in the design of the consent process (Koops BMJ 2002; 325: 415) and we are delighted to welcome Heather Goodare to the Steering Committee as our Lay Person Representative. Heather’s husband had a stroke and we will value her perspective during the next few busy years of the trial.

A letter published in the NEJM in response to the ECASS-III publications caught our eye, especially as one of the authors was an old colleague from Newcastle upon Tyne. These physicians, from Dublin, were commenting on the unnecessary age limits in ECASS-III (an age cut off of 80 years of age has been routine for most previous trials). We, from the trial office, have been in contact and hope that this will help persuade our colleagues in Eire to join the trial. If you know of any other potential new centres, please let us know, as we are still keen to expand our trial centre numbers.

Profile: Heather Goodare, the Lay Representative on IST-3 Steering Committee

There has been so much to tell you in recent newsletters that we haven’t had a chance to tell you about our new Steering Committee (TSC) member, Mrs. Heather Goodare as the lay representative. IST-3 pioneered lay involvement in stroke trials with Richard Lindley’s work with groups of lay people (patients, carers, and older people at risk of stroke) who helped develop the patient information leaflets and consent forms for the trial. Until Heather joined the TSC, we have not had continuing lay involvement in the trial. That deficiency is now rectified with Heather’s appointment!
Profile of Heather Goodare, continued;

Heather knows a lot about clinical trials, both as a participant and commentator. She is a reviewer for the NHS Health Technology Assessment group, is a member of INVOLVE (the UK organisation about involving consumers in health research), and has also done some research herself on improving cancer care in West Sussex (Goodare H, Nadim LM. Journal of holistic healthcare; 2006; 3 (4): 24-31). Though she describes herself as ‘an absolute beginner in matters to do with Stroke’, she is being typically modest; she has unfortunately had to learn a lot about the condition, as her husband Ken has had a stroke.

I met Heather and Ken at a focus group discussing neurological services in Edinburgh in 2008. It was immediately apparent that Heather would be an ideal lay representative for the TSC. When I approached Heather with the suggestion that she join, she readily agreed. Heather attended her first TSC meeting in November 2008. She made valuable contributions to the discussions. She has also recently reviewed the patient information leaflets, and made helpful suggestions about how we could further improve them. So please welcome Heather as a new member of the IST-3 Collaborative Group.

Peter Sandercock
January 2009

IST 3 at Norfolk and Norwich University Hospital

We recruited our first patient into IST 3 in July 2006. We took a while in the planning stages. There was discussion with radiology, A&E, pharmacy. At that time we found “walking through” the patient journey was useful, especially in prediction of potential problems. What works well in the system which evolved:

- Single phone call to a DECT phone carrying nurse from A&E
- Very rapid removal of patient from A&E (good for 4 hr targets!)
- Appropriate CT requests, accurately completed
- We transfer the patient by trolley to CT then the Stroke Unit. This significantly reduces all times in radiology – they like this!
- Immediate and ongoing discussion with patients and relatives by experts

The trial has been well supported by all the team here. Primarily we believe it to be an important trial asking relevant clinical questions. Other benefits:

- Team – significant empowering of nurses and doctors in acute stroke care
- Different to standard ward work, adds dynamism to the day
- Has forged good links between Neurology and Medicine for Elderly physicians
- Stroke Research Network (SRN) portfolio trial. Funding and recognition for trials is important and this is a big trial to the network. Involvement is seen favorably be either the SRN or Comprehensive Local Research Networks (CLRN)
- Is providing an excellent framework and training for the running of a 24hr stroke thrombolysis service. We are in the middle developing this

While we can’t claim it has been all plain sailing I have emphasised the many positives the team feel rather than the few negatives.
NEW CENTRES

Our thanks and congratulations go to the following centres for randomising their first patients to the IST-3 Trial:

- Dr Giuseppe Rinaldi and the Team at Azienda Ospedaliero – Universitaria, Foggia, Italy
- Dr Piotr Sobolewski and the Team at SPZZOZ w Sandomierzu, Sandomierz, Poland
- Dr Martin James and the Team at Royal Devon & Exeter Hospital (Wonford), Exeter, UK

Fantastic work!

FIRST RANDOMISATIONS!

Our thanks and congratulations go to the following centres for randomising their first patients to the IST-3 Trial:

- Dr V.T. Cruz and the Team at Hospital de S. Sebastião, St. Maria da Feira, Portugal
- Dr N Checcarelli and the Team at Ospedale Valduce di Como, Como, Italy
- Dr C Church and the Team at University Hospital of North Durham, Durham, UK
- Dr F Buchwald an the Team at Malmö Hospital, Malmö, Sweden

WELL DONE!

Request for copies of Site Staff Signature & Delegation Logs

As you know, to comply with the principles of Good Clinical Practice, each centre is required to complete and maintain a Signature and Delegation Log. This Log records the details of all staff that are working or have worked on IST-3 and records the specific study tasks that each member of site staff was delegated to perform by the Principal Investigator. It is the responsibility of the Principal Investigator to ensure this log is completed and signed by each member of staff delegated tasks in IST-3 (including the allocated research nurse, pharmacist and radiologist). Any changes to the team MUST be recorded. A copy of the delegation and signature log should be sent to the Co-ordinating Centre in Edinburgh and any additional copies sent when changes are made. The original copies should be stored in your IST-3 Site File.

We recently audited the number of Signature and Delegation logs we have received and there are a number of centres where we have not yet received this information.

We would like to request that if you have not yet completed and returned a Delegation Log to us, please do so as soon as possible. A copy of the current IST-3 Signature and Delegation Log has been included with this Newsletter or you can access an electronic copy via the website www.ist3.com.

Thank you for your co-operation.
**IST-3 Delegation Log**

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<th>Print Full Name &amp; Title</th>
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<th><strong>Key Delegated Study Task(s)</strong></th>
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*Identification of study role includes but is not limited to sub-investigators, study nurses, pharmacist (when appropriate) and data recorders. List individuals delegated significant study-related tasks (ICH GCP 4.1.5). Signatures/Initials required for all persons authorised to make entries and/or corrections to Case Report Forms (ICH GCP 8.3.24) * Identify key study tasks when delegated by the investigator. Examples of key delegated study tasks could include:

1. Obtain Informed Consent
2. Obtain Medical History & Perform Physical Examination
3. Inclusion/Exclusion Assessment
4. Medical care of patients
5. Administration of rt-PA
6. Completion of IST-3 Treatment & 7 Day Form
7. Data Query Completion
8. Pharmacovigilance Reporting
9. Set up & Maintenance of Investigator Site File
10. Drug Dispensing
11. Drug Accountability
12. Other ______________________
13. Other ______________________
14. Other ______________________

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