

THE IST-3 TIMES

January 2007



EDITORIAL

Professor Richard Lindley, Co-Chief Investigator



Happy New Year to you all!

This year will be an important one for IST-3 as we are predicted to become the largest-ever randomised trial of thrombolysis for stroke during this year of 2007. ECASS-II currently holds the record with 800 patients recruited, and at the time of writing (end of December), IST-3 recruitment was at 688, therefore only another 113 patients are required to overtake it. This, of course, is still only a fraction of our target of 6000 which we believe will be required to make a big change in how people perceive thrombolysis. Treatment is still very limited around the world, and proof of effectiveness for a wider group of patients is required before thrombolysis becomes universally accepted. The main uncertainties of the time window, and differences in effects of treatment by stroke subtype and age dominate the rationale for the trial, and it is interesting to note that the many observational studies published since IST-3 was designed have not resolved these uncertainties.

If IST-3 results are positive, many more patients will benefit from rt-PA

Providing the hospital service has acute stroke expertise, a CT scanner and access to rt-PA, we believe thrombolysis has enormous potential to improve the outcome of many tens of thousands of people around the world. However, if treatment is to be widely available we need seriously reliable data on which to base treatment decisions. The IST-3 group have undertaken a large portfolio of research to support the trial rationale and design, ranging from new ways to assess and describe acute brain imaging, investigation into the ethics of treatment decisions, to the study of the “science” behind the art of acute stroke diagnosis. In addition, the trial continues the IST philosophy of using streamlined trial design to maximise scientific gain and reduce the work of busy clinician researchers. The trial has already generated a wealth of potential data and will continue to do so.

Threats to IST-3 and other academic trials

There are many threats to trials such as IST-3. The increase in the burden of research regulation has slowed recruitment into IST-3 and many other academic investigator-led studies. Industry-led trials continue to be under-powered and have not led to major advances in acute stroke care. The financial incentives to do industry-sponsored trials (often used to fund essential staff and equipment in under-funded stroke services), has attracted many good centres away from academic led studies. We recognise these realities of stroke research in the 21st century, but hope that stroke research centres will ‘steer a middle road’ and continue to collaborate in important academic led trials, such as IST-3 but still participate in new industry led studies. I hope 2007 continues to be a successful period for the trial and let’s see if we can become the world’s largest stroke thrombolysis study early in the year!

NEWSFLASH: 700TH PATIENT RECRUITED! (see page 4)

**RECRUITMENT AT 16th
January 2007**

**NUMBER OF PATIENTS
RECRUITED**

UK	5
Norway	6
Poland	2
Italy	0
Canada	0
Belgium	0
Austria	0
Australia	0
Sweden	4

Total 17

**TOTAL NUMBER
OF PATIENTS
RECRUITED
TO DATE:**

701

**NUMBER OF CENTRES
PER COUNTRY**

UK:	21
Sweden:	9
Poland:	5
Norway:	9
Italy :	12
India :	1
Canada:	1
Belgium:	2
Austria:	1
Australia:	10

Wirral Hospital NHS Trust

Hello from the Wirral!

Our Stroke Team has recently expanded with the appointment of Dr. Debbie Lowe joining Drs. Graeme Sangster and James Barrett on the Wirral. They lead a seamless service across 12 acute and 20 designated stroke rehabilitation beds. Recent developments have included; improved access to TIA clinics, timely investigations and a reduction in the number of patients requiring hospital admission. There are plans to increase the number of acute beds to maximise the number of patients admitted directly to the stroke service. We have been recruiting patients into the IST trial since 2001 and since November 2005 have recruited 4 patients into the open phase. Three were randomised to control and one to thrombolysis. In addition, we routinely thrombolysed within three hours of acute onset of stroke (Monday – Friday). As a result three patients have been treated successfully with routine thrombolysis during the last twelve months. Further Information contact:

stroke.co-ordinator@whnt.nhs.uk & www.wirralstroke.nhs.uk



**IST-3 Portugal Collaborators' meeting, Porto
24th November 2006**

Dr Manuel Correia organised a very successful meeting of the centres in Portugal interested to join the study. The meeting was held during the Portuguese Neurological Society. Over 20 people attended, with at least one person from each of the neurological centres in Portugal. All of the centres have experience of thrombolysis, have participated in SITS-MOST, and want to participate in the trial to help answer the IST-3 question 'do patients treated outside the licence benefit from rt-PA?' Peter Sandercock presented the trial's rationale, the protocol and the progress with the trial to date. Manuel Correia then discussed the local problems that need to be solved to get the trial started (mainly insurance). There was then a lively discussion, with plenty of positive support for the trial.



IST-3 collaborator audience



Peter and Manuel discussing a question from the collaborators

WEB RANDOMISATION

We are delighted that so many of our centres are using the IST-3 web randomisation system. Since it went live on the 12th April 2006 an impressive 108 out of 165 patients randomised were randomised via the web. Feedback from our centres regarding the system has been very encouraging and positive. The web system is user friendly and definitely a less stressful way to randomise patients!

So if you haven't used the system yet and you have access to the internet, give it a go!

WWW.IST3.COM

You can practice using the web randomisation system (click on the randomisation link)

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Thrombolysis

The Third International Stroke Trial (Thrombolysis)

A large randomised controlled trial of thrombolysis with intravenous recombinant tissue plasminogen for acute ischaemic stroke within 6 hours

[Randomise a Patient](#)

Improve your acute stroke imaging interpretative skills!
[See- BASP CT Training Series](#)
[ACCESS Study - The Acute Cerebral CT Evaluation Study](#)

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Practice

To practice randomisation click on this link ("Try Randomisation"), which will take you to this page.

Randomise a Real Patient

To randomise a real patient, make sure that you can answer **ALL** the questions on the Randomisation Notepad and click on this button "Randomise a Patient".

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Thrombolysis

The Third International Stroke Trial (Thrombolysis)

[\[ISRCTN2576561 \]](#)

Practice Randomising a patient into the IST3 Trial

Please login

Country Number 2 digits
Hospital Number 3 digits
Clinician Access Code 4 digits
Is this a genuine patient?

This is a practice randomisation! No patient will be randomised into the trial.

If you have not yet joined the trial use 99 as Country Number, 999 as Hospital Number and 9999 as Clinician Access Code

otherwise - if already an CLOTS collaborator, use your designated trial codes as specified in your manual.

If possible, before starting have a randomisation questionnaire that has been fully completed.

Entries will be lost if left unattended for 20 minutes.

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**THE IST-3
CO-ORDINATING CENTRE**

Neurosciences Trials Unit,

**Edinburgh, Scotland,
EH4 2XU**

Telephone:

++44 (0) 131 537 2793

Fax:

++44 (0) 131 332 5150

Email:

ist3@skull.dcn.ed.ac.uk

Website:

www.ist3.com

Co Chief Investigators:

Prof Peter Sandercock

Prof Richard Lindley

Trial Co-ordinator:

Karen Innes

Centre Co-ordinator:

Alison Clark

Trial Programmers:

Vera Soosay

David Buchanan

Statistician:

Dr Steff Lewis

Trial Support Team:

Sheila Grant

Janie Hunter

Anne Fraser

Anne Williamson

NEW CENTRES

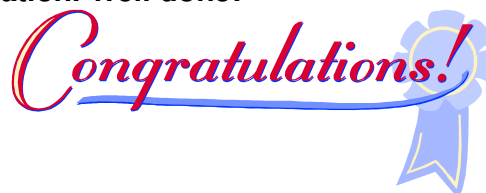
Our thanks and congratulations go to the following centres for all their hard work in getting through the start-up procedures and are now ready to start randomising:

- Dr John Paterson and the team at Scarborough Hospital, Scarborough, UK
- Professor Chris Gray and the team at Sunderland Royal Infirmary, Sunderland, UK
- AProf Helen Dewey and the team at Austin Health – Repatriation Campus, Heidelberg Heights, Victoria, Australia

PATIENT 700 RECRUITED!

Congratulations to Dr Bo Hojeberg and the team at Capiro S: t Goran Hospital, Stockholm, Sweden who recruited IST's 700th patient!

Your prize is a free delegate place at the European Stroke Conference in Glasgow in May 2007 with a £100 towards accommodation. Well done!



We are delighted at the rate of recruitment to the trial but we do have a long way to go before we reach our trial target.

This is your trial it will only succeed with your help so get randomising and think :-

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FUTURE IST-3 COLLABORATORS MEETINGS

- 23/03/07 Norway, Oslo
- 30/03/07 Sweden, Stockholm
- 04/05/07 Canada, Halifax

Once confirmed, details of these meetings will be available soon on the IST-3 website:

www.ist3.com

