Consent for Thrombolysis for Acute Ischaemic Stroke

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**Purpose**

New treatments for older people must be evaluated in randomised controlled trials. Randomised controlled trials for some conditions such as stroke, cardiac arrest, head injury or dementia, are complicated as the patients often lack appropriate mental capacity. Consent laws for such patients differ between regions. Our aim was to describe the consent process for patients in a trial of emergency stroke treatment.

**Methods**

The Third International Stroke Trial is a multi-centre, randomised, controlled trial of intravenous recombinant tissue plasminogen activator for patients with acute ischaemic stroke who can be treated within 6 hours of symptom onset. IST-3 doesn’t exclude older people and thus is unique amongst stroke thrombolysis trials which to date have all excluded those over 80 years of age. The eligibility criteria are shown in the box. Written consent is obtained when possible, but verbal consent, or “assent” by relatives or other proxy, or “waiver” of consent (if the patient is acutely mentally incapacitated and no proxy is available) has been approved in some centres. The method of consent is recorded on the 7 day hospital form for each patient in the trial. We report the method of consent for the first 300 patients.

**Results**

Consent was: written for 69 (23%) patients; verbal for 30 (10%); assent for 196 (65%); and waiver for 2 (1%) (data awaited on 3). The proportion of patients with the different consent procedures is shown in the Table and the Figures. It can be seen that the stroke impairments and stroke subtype are a very important determinant of feasible consent procedures.

**Discussion**

Patients with severe strokes are the least likely to provide written informed consent and may be excluded from participation in the trial in some regions, yet these patients may have the most to gain from new stroke treatments. Flexible consent procedures are required for some medical conditions.

**Acknowledgements**

IST-3 is has been supported by the UK Stroke Association, the Healthcare Foundation and is now funded by the UK Medical Research Council.

The Australian centres of IST-3 are supported by the Heart Foundation until the end of 2006.

For further information see http://www.ist3.com