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ENOS NEWS

Recruitment 11/06-02/08

UK	**196**
Lincoln	*39*
Aberdeen	*19*
Nottingham City	*18*
Bishop Auckland	*18*
Boston Pilgrim	*15*
Blackpool Victoria	*14*
Stockport Steppg Hill	*12*
Stoke-on-Trent	*11*
Edinburgh Western	*9*
Glasgow Monklands	*9*
Newham General	*5*
Doncaster	*3*
Wolvhmptn, New Cross	*3*
Royal Devon & Exeter	*3*
Torbay	*2*
Yeovil District Hospital	*2*
Liverpool Aintree	*2*
Harrogate	*2*
Scarborough	*2*
Borders Melrose	*2*
Scunthorpe	*1*
Staffordshire General	*1*
Edinburgh Royal	*1*
Glasgow Royal	*1*
London Kings	*1*
Glasgow Stobhill	*1*
China	**90**
Wenzhou	*85*
Tian Tan	*5*
New Zealand	**18**
Dunedin	*15*
Auckland	*1*
Hawkes Bay	*1*
Hutt Hospital	*1*
Singapore	**12**
Sri Lanka	**11**
Canada	**10**
Malaysia	**5**
Poland	**7**
Australia	**1**
Italy	**0**
Philippines	**0**
Hong Kong	**0**
Belgium	**0**

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The Newsletter for the Efficacy in Nitric Oxide Stroke Trial
Web: www.enos.ac.uk Email: enos@nottingham.ac.uk

Continue/Stop

Feedback from our recent recruitment questionnaire tells us there is sometimes concern over the continue/stop arm of ENOS. As such, it is worthwhile reviewing the evidence that already exists in this area and the potential benefits/drawbacks of continuing or stopping pre-stroke antihypertensive medication.

There are currently no published trials giving us an answer. There is evidence about the effects of some agents when started for the first time in the acute stroke period, and this complicates things, as agents may well have different drawbacks and benefits. For example, calcium channel blockers may be harmful. With a lack of evidence we need to consider the possible benefits and drawbacks.

Continuing pre-stroke antihypertensive medications may be a good thing as they may prevent blood pressure from rising steeply after a stroke. However, higher blood pressure may be helpful if it maintains cerebral perfusion pressure in ischaemic stroke. If patients are poorly compliant with their medication before the stroke, giving the drugs routinely in hospital may cause a relatively large fall in blood pressure that may be harmful. Some agents may be harmful in acute stroke.

Stopping pre-stroke antihypertensive medications may be beneficial if some of the agents are potentially harmful. However, it may be better to maintain lower blood pressure and sudden withdrawal may cause an additional rise in blood pressure. In the light of these arguments, it is sensible to conduct a trial to determine the best course of action.

The Data Monitoring Committee has assessed un-blinded ENOS data on 11 occasions to date and has no concerns about the continuation of this aspect of the trial. We hope that you are happy to continue to randomise patients into the continue/stop arm of ENOS.

Congratulations to....

- Stobhill Hospital, Royal Infirmary, Glasgow and Harrogate District Hospital, UK for randomising their first ever ENOS patients.

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The Stroke Association
The University of Nottingham

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ENOS Protocol update

The ENOS protocol v1.3 16 August 2001 has been updated to v1.4 16 November 2007. The updated version has now been approved by MREC and MHRA so please update your paperwork to v1.4. Associated with this are new PIS, Consent/Assents v2.10 and a new GP letter v1.3. All forms have been sent to existing and prospective centres and are available for download from the ENOS website forms page.

The information within the new protocol has not changed the trial in any way, but provides clarity on certain issues. The competent authority for the UK and Ethics Committee have fully endorsed the updated ENOS protocol. This means the trial design and all trial procedures as set out in these documents have been re-examined and approved.

Physician assent has been added to the protocol and approved, so centres may adopt this if required.

European Stroke Conference, Nice, May 2008

- **Stand** - ENOS will be represented at a stand at the ESC in Nice, May 2008. We look forward to meeting with collaborators that are attending.
- **Investigator Meeting** - We are also hosting a joint Investigator Meeting with IST-3 on Wednesday 14 May, 5.30-7.30pm at the NH Hotel, opposite the Acropolis conference centre.

Tips of the month

CT Scans - Please note that the day 7 form asks for information on the baseline scan, not day 7 scan. We do not require non-brain scans.

SAE Forms – We still collect SAEs after patients have been discharged from hospital, for up to 90 days of randomisation. All deaths need an SAE form to be completed.

Baseline Form – The online form has been altered so that “anterior” or “posterior” cannot be selected.

******Recently Updated Forms******

- **Work in Practice documents (previously named SOPs)**: Blood pressure readings v1.6, Password change v1.0, Continue/stop v1.0, Staff Cover ICC v1.2, 90 Day Follow Up v1.5, 90 Day Follow Up Finding Missing Patients v1.1, 90 Day Follow Up, Postal Questionnaire v1.1
- **PIS, Consent, Assent** v2.10
- **Protocol** v1.4, **GP Letter** v1.3.
- **Follow Up:** 90 Day Telephone v3.4, 90 Day Post v1.3, 90 Day Follow Up FAQ v1.0, Follow Up GP Letter Pain v1.0, Follow Up GP Letter Depression v1.0, 90 Day Missing Patients v1.1

All forms can be downloaded from the web-site (Documents page after login).

ENOS now has 59 centres in 13 countries.

More centres are very welcome.