December 2005

Issue 27

ENOS NEWS

The Newsletter for the 'Efficacy of Nitric Oxide in Stroke' Trial

Headlines:

- Earlier recruitment
- New phone numbers
- BP recordings
- DMC
- Events reporting

Current Recruitment 416

Congratulations to Dr Macleod's Team in Aberdeen for recruiting 2 patients last month

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Earlier recruitment needed

Investigators are asked to randomise patients as soon as possible after presentation to hospital. At present a high proportion of patients are enrolled greater than 24 hours after symptom onset. A long recruitment window does not mean a longer time to recruit.

New phone numbers

The telephone numbers at the ENOS Office are due to change from December 19th 2005. All investigators will receive a new contact details sheet to confirm the new numbers which are also shown in this newsletter. Please use the new telephone number +44 115 823 1769 and fax number +44 115 8231771 from 19.12.05 onwards.

Blood Pressure recordings

When measuring blood pressure following randomisation, investigators are reminded to take two separate blood pressure readings, using the OMRON machines provided, at approximately 60 to 90 minutes following patch application. This is to ensure that blood pressure recordings reflect the peak blood pressure effect of GTN.

Data Monitoring Committee

Excellent news : The Data Monitoring Committee met on the 1st November 2005 to review data on the first 393 patients randomised. In reviewing the safety and efficacy data the Committee had no concerns and recommended the trial continue recruitment.

Event reporting

We would like to remind investigators to record any events, such as deterioration, recurrent stroke or thromboembolic events clearly on the day seven case report form. Any recurrent stroke should be classified as ischaemic or haemorrhagic if at all possible.
In the event of a patient suffering an adverse event that leads to death please can investigators complete the adverse event form prior to submitting the hospital events form. As all Investigators are no doubt aware it is vitally important to report adverse events in real time as soon as the investigator becomes aware of them, in order to comply with Good Clinical Practice.