

June 2004

Issue 18

ENOS NEWS



Headlines:

- COREC from
- Tip of the Month
- Investigator Meetings
- Congratulations

ENOS milestones:

- 1st patient – 20/7/01
- 2nd site – 26/12/01
- Largest GTN trial (n=91) – 17/3/03
- Bigger than metanalysis (n=128) – 8/6/03
- 200th patient – 13/1/04
- Next DMC – 2/11/04

Recruitment total: 244

- Aberdeen - 21
- Bishop Auckland - 15
- Boston - 2
- Cheltenham - 0
- Halifax (Canada) - 10
- Liverpool - 4
- Mansfield - 0
- Manila - 0
- Nottingham (City) - 82
- Nottingham (QMC) - 9
- Manila (Philippines) - 2
- Sheffield (Hallamshire) - 1
- Singapore - 52
- Sydney (Canada) - 1
- Rhyl - 0
- Warsaw (IPN) - 40
- Warsaw (MMA) - 6

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

ENOS COREC form – UK only

Many of you will be aware that UK ethics applications are now required to be submitted on a standard COREC form. This form is based on previous MREC and other REC forms and is compatible with the requirements of ICH-GCP

and the European Directive on Clinical Trials. We are pleased to announce that a version has now been produced specifically for the ENOS trial. In future this will be available to all new UK centers in order to help speed them through the ethics application process.

Tip of the month

It is very important that the results of Carotid Doppler scans are documented on the ENOS 'Discharge' form. This is of great relevance to ENOS because patients with significant carotid stenosis may respond differently to active BP lowering than patients without carotid stenosis. Consequently, the discharge form

should always be left until the results of carotid Doppler scans are known. Also, the % stenosis should be entered in the appropriate box on the form. Please note that if your Doppler reports give the degree of stenosis as a range rather than a specific value, then the middle value should be entered, e.g. 70-90% stenosis would be entered as 80%.

ENOS Investigator meetings

The ENOS trial recently held an Investigator Meeting at the European Stroke Conference in Mannheim, Germany and at the World Stroke Conference in Vancouver, Canada. We are

grateful to the many representatives from around the world who were able to attend and helped make both of these meetings a great success.

ENOS CT scans

Could investigators who haven't returned their CT scans yet please do so as soon as possible. It is best to send them

in electronic format, saved as a DICOM file. Advice can be obtained from the trial coordinating centre on how to do this.

Congratulations

Congratulations to our two new UK centres in Edinburgh and the Isle of Wight. We would like to welcome them to the ENOS trial and we wish them well in

recruiting their first patients shortly. Also, we would like to congratulate our new centre in Manila, Philippines for recruiting their first couple of patients into ENOS.