ENOS NEWSLETTER

Issue 1, July 2001

Welcome to ENOS Hello and welcome to all centres who have expressed an interest in joining the ENOS trial. We will be issuing regular newsletters throughout the trial from the international co-ordinating centre at Nottingham City Hospital in the UK. Your comments and suggestions will always be welcome; please contact us at the address below.

What is ENOS? The ENOS acronym stands for "Efficacy of Nitric Oxide in Stroke". (If you wonder why we chose ENOS, a non English word, it is because vascular nitric oxide is synthesised by the enzyme endothelial nitric oxide synthase, otherwise called eNOS!). The study is a prospective, international multicentre, randomised, parallel-group, blinded, controlled, collaborative trial to investigate the safety and efficacy of treatment with transdermal glyceryl trinitrate, a nitric oxide donor, and of continuing or stopping prior antihypertensive therapy, in patients with acute ischaemic or haemorrhagic stroke. Previously independent adult patients who are conscious and have residual limb weakness are eligible for enrollment. Treatment is initiated within 48 hours of stroke onset and is given as daily glyceryl trinitrate patches for 7 days. A CT scan is required within 7 days of randomisation to confirm the type of stroke. The trial will be conducted over a secure internet site (see below for further details). Early follow up is performed locally over the 7 days of treatment, including blood pressure, early stroke events and adverse events. Central follow up will be performed by telephone by the trial co-ordinating centre at 3 months. The primary outcome is combined death or dependency (modified Rankin Score >2). A summary of the study protocol can be found on our web-site (see below).

The Web Site For maximum efficiency and speed the ENOS trial will be conducted over a secure internet site. This will provide access for downloadable documents, emails, and web-based randomisation, data registration and a conduit for reporting serious adverse events. A demonstration site will shortly be available for trying and commenting on. If you would like to test it out please let us know including the IP address of your computer and we will set this up - the IP address is needed as part of the security system.

Progress With the appointment of our Trial Medic, Dr Mark Willmot, we have now completed our investigating team. Mark will be helping in setting up the trial and will be visiting participating centres later this year. Professor Philip Bath will be overseeing the trial as Principal Investigator. Other members of the team are Chris Weaver (Trial Manager), Jo Leonardi-Bee (Trial Statistician), and Cherry Baker (Secretary).

We now have LREC approval for ENOS at Nottingham City Hospital and intend to start recruiting patients within the next fortnight. We are in the process of submitting for MREC approval and will update you on this in following newsletters. Centres in Canada and Australia have also submitted for ethics approval.

In addition to this, our ENOS website is nearing completion and we shall be testing this rigorously prior to going online.

Another project we have ongoing is the development of a 'welcome pack' which we are planning to send to participating centres when they join the trial. This will contain the full protocol and various forms required for registering the centre and obtaining full access to the website.

Finally, in order to keep you up to date on ENOS, we will be sending newsletters regularly by email to participating and other interested centres.

Contact details ENOS Trial Office, Division of Stroke Medicine, University of Nottingham, City Hospital campus, Nottingham, NG5 1PB. Tel: +44 115 840 4857. Fax: +44 115 840 4795.
Email: enos@ nottingham.ac.uk. Website: www.nottingham.ac.uk/stroke-medicine/.