

Recruitment

1 Nov 06 to 31 Oct 07

UK	137
Lincoln	27
Aberdeen	18
Nottingham City	14
Stockport Steppg Hill	12
Bishop Auckland	12
Boston Pilgrim	9
Stoke-on-Trent	9
Edinburgh Western	9
Glasgow Monklands	6
Blackpool Victoria	5
Newham General	4
Doncaster	2
Torbay	2
Wolverhampton	2
Royal Devon & Exeter	1
Scunthorpe	1
Staffordshire General	1
Yeovil District Hospital	1
Edinburgh Royal	1
Liverpool Aintree	1
Glasgow Western	0
Stirling Royal Infirmary	0
Oxford	0
Antrim	0
Borders Melrose	0
Ulster	0
Derby Hospitals	0
Chesterfield	0
Truro	0
China	77
Wenzhou	72
Tian Tan	5
New Zealand	17
Dunedin	14
Auckland	1
Hawkes Bay	1
Hutt Hospital	1
Singapore	12
Sri Lanka	8
Canada	6
Poland	3
Australia	1
Malaysia	3
Philippines	0
Hong Kong	0
Belgium	0

The Newsletter for the Efficacy in Nitric Oxide Stroke Trial

Web: www.enos.ac.uk Email: enos@nottingham.ac.uk

UK Investigator Meeting

Thank you to all investigators that attended the UK Investigator Meeting at the University of Nottingham in September. We had a positive, well attended meeting with excellent feedback.



Issues raised for discussion that are likely to be of interest to all sites were:

- An updated version of the protocol is under development and we will submit this for approval later this year. In the interim, a letter addressing commonly raised issues by prospective sites, R&D, pharmacy and others is now available on the ENOS website.
- Patients do not need a pre-randomisation CT scan to enter the trial. If they have had a pre-randomisation scan, we would like a second scan to be done at day 7, for which we will pay £80.
- It will soon be possible for Investigators to change their ENOS password to something more memorable. This will need changing every six months and rules on length and characters will apply.
- The ENOS demo website contains a link to downloadable documents for sites that do not have active ENOS passwords.
- Open label thrombolysis patients can be included in ENOS.
- ENOS is single blind to the patient. A gauze dressing should be used. The MREC approval letter for single blinding is on the website.

ENOS Competition and Prizes

Continue or Stop for 2008?! We are offering a prize for the most creative New Year's Resolution – what will you continue or stop for 2008? Entry forms can be downloaded from the ENOS website and emailed to enos@nottingham.ac.uk.

The centre that recruits the **800th ENOS patient** will be awarded a prize of free registration at the next European Stroke Conference in Nice, France May 2008.

A prize for recruiting **10 ENOS patients between 1 Nov and 31 Dec** of £500 will be awarded to each centre that recruits 10 patients in this time. NB The prize money will only be transferred once all documents and CT scans have been received.

ENOS Trial Office

Division of Stroke Medicine
Clinical Sciences Building
Nottingham University
Hospital NHS Trust
Hucknall Road
Nottingham
NG5 1PB
Tel +44 115 823 1770
Fax. +44 115 823 1771

Chief Investigator
Philip Bath
+44 115 823 1768

Trial Medics
Gillian Sare
+44 115 823 1769

Tim England
+44 115 823 0288

Trial Manager
Sally Utton
+44 115 823 0287

UK Centre Coordinator
Tanya Payne
+44 115 823 0286

**International Centre
Coordinator**
Shirley Macalpine
+44 115 823 1770

Follow Up Coordinator
Sharon Ellender
+44 115 823 0289

Trial Statistician
Laura Gray
+44 115 823 1772

**Data and Imaging
Officer**
Lida Kaur
+44 115823 1776

Research Secretary
Yvonne Smallwood
+44 115 823 1770



Congratulations to....

- Blackpool Victoria Hospital, UK, Staffordshire General Hospital, UK and Royal Devon and Exeter Hospital for randomising their first ever ENOS patients, to Aintree, Liverpool for randomising their first patient since 1 Nov 06 and to Blackpool Victoria for recruiting their first five patients and achieving the £100 bonus.

TOAST

A reminder about the TOAST classification on the hospital events form. This is the section that asks you to choose a likely aetiology for the stroke from probable large vessel, small vessel, cardioembolic and other. This is sometimes being filled out incorrectly. In general, probable 'cardioembolic' should be selected if the patient has AF or other cardiac cause of emboli. Probable 'small vessel' stroke should be selected if a lacunar stroke is seen on the scan and/or the patient has a lacunar syndrome, i.e. pure motor/sensory strokes in the absence of cortical signs (such as true dysphasia, neglect, hemianopia). 'Large vessel' disease should be selected if a patient has had a stroke of the TACS/PACS variety where it is reasonable to assume atherosclerosis is the cause (e.g. carotid disease, advanced age, risk factors). 'Other' accounts for rare causes or unexplained stroke (e.g. dissection, unexplained stroke in a young patient). Please note these are not mutually exclusive categories i.e. a patient with a lacunar stroke who happens to have AF and ipsilateral severe carotid stenosis would have all three "yes" boxes ticked. This is not the same method of classification that is used for the PERFORM trial. If in doubt, please feel free to phone the ENOS office to ask.

Tips of the month

- Weight Estimate** - The baseline form has been updated to include an estimate of weight. We would eventually like to analyse BP response to GTN with adjustment.
- Days** - Please note that Baseline (day 0), refers to everything prior to the first patch (or no patch) with gauze dressing, being applied. The application of patch (or no patch) and gauze dressing marks the start of Day 1. Day 2 starts when the patch (or no patch) and gauze dressing are changed. Day 1 may be less than 24 hours.
- CT uploads** - There are two systems on the ENOS website to use for CT uploads; please try the java upload first. If this does not work, use the alternative. If this does not work, contact the ENOS Office.

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

- SOPs:** Staff cover at International Coordinating Centre v1.1, Training records v1.0, Collecting and freezing blood samples v1.1, Source data documentation v1.0, Version control of documents v1.0, SAE v1.7, Patch application v1.3, Payments to centres v1.0, Site Start Up v1.9, Baseline v1.7.
- Letter to Nursing Home v1.0, Site Monitoring Template letter v1.0.
- Baseline form v3.3, Day 7 Form v3.8, SAE form v2.9, Signature log v1.1, Data correction form v1.1.

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

**ENOS now has 52 centres in 12 countries.
More centres are very welcome.**