



Recruitment to 4 Sep

International 445

Australia 8

Box Hill, Melbourne 8
Canberra 0

Canada 28

Halifax (NC) 27
Cape Breton 1

China 103

Tian Tan (NC) 16
Wenzhou 87

Hong Kong 4

India 1

Italy 0

Malaysia 7

New Zealand 30

Hawkes Bay (NC) 1
Dunedin 25
Hutt Hospital 3
Auckland 1

Philippines 16

Poland 90

Inst Psyc & Neur (NC) 81
Military Med Acad 9

Singapore 144

Sri Lanka 14

The Newsletter for the Efficacy in Nitric Oxide Stroke Trial

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

1,000th ENOS Patient

Thank you to all Investigators for helping us reach the 1,000th ENOS patient. The patient was recruited by the team at Nottingham City Hospital. Lynn Stokes, Research Nurse at Nottingham will attend the UK Stroke Forum, Harrogate. We have also awarded the £500 prize to the centre that recruited patient 1,001, which is Dunedin Hospital, New Zealand, to use at a conference of their choice.

Congratulations to....



- All India Institute of Medical Sciences, Delhi for recruiting the first ENOS patient in India.
- Countess of Chester Hospital, UK for recruiting their first ENOS patient only 7 days after start up.
- John Radcliffe Hospital, Oxford, UK for recruiting their first patient.
- ENOS Trial Medic, Dr Gillian Sare on her recent marriage.

ENOS Database

Principal Investigators (e-mails)

Following a request, Principal Investigators now receive an e-mail message alerting them to when a new patient for their centre is entered into the database.

Baseline Form

There have been a few occasions when an incorrect age for a patient has been entered. A change will be made to ask for the Date of Birth to be entered on the Baseline form rather than Age. It must be stressed that the Date of Birth will **NOT** be stored in the database. The Date of Birth will only be used to calculate the Age and it will still be the Age of the patient that is stored in the database.

90 Day Follow-up form changes

1. In those cases when a patient has deceased but no related Serious Adverse Event record exists within the database, any available death-related data will be collected. We will contact you for information.

2. For patients that have had multiple events since discharge that has hospitalised them, each of the individual types of event can be entered. For 'Other Hospitalisation' events, descriptive text can be entered.

3. A new question has been introduced asking if the patient can recall undergoing carotid endarterectomy or carotid stenting.

Recruitment to date

UK 556

Aberdeen	60
Barnsley	2
Bishop Auckland	47
Blackpool Victoria	20
Borders Melrose	3
Countess of Chester	2
Derby Hospitals	14
Doncaster	6
Edinburgh Royal	4
Edinburgh Western	11
Glasgow Royal	4
Harrogate District	4
John Radcliffe, Oxford	2
Kings College London	1
Lincoln	43
Monklands Glasgow	10
New Cross Wolverhampton	4
Newham General	23
Nottingham City	169
Pilgrim Boston	25
QMC Nottingham	23
Royal Devon & Exeter	8
Royal Hallams Sheffield	1
Royal Preston	2
Scarborough	5
Scunthorpe	2
Southport & Ormskirk	1
St Marys Isle of Wight	2
Staffordshire General	1
Stockport Stepping Hill	15
Stobhill Glasgow	2
Stoke-on-Trent	13
Torbay	3
University Hosp, Aintree	7
University Hosp, Coventry	1
Victoria Hosp Kirkcaldy Fife	7
Yeovil District Hospital	9

1,001

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
Email: enos@nottingham.ac.uk

Investigators (e-mails)

If, at the 90 Day follow-up, a patient is recorded as having undergone carotid endarterectomy or carotid stenting but no corresponding Hospital Event (HE) data has been recorded, an e-mail message will be sent. The e-mail message will ask for a carotid doppler or MRI report to be faxed to the ENOS office or a HE form to be completed.

There is a legal responsibility to collect all Serious Adverse Events (SAEs). If it is determined that an SAE appears to be missing, an appropriate e-mail message will be generated. It is appreciated that such an SAE may be waiting to be input by the local Investigator.

For patients recorded as deceased, but with no corresponding SAE, an e-mail message will be generated containing any available death-related information that was available to the 90 Day Investigator. In such cases, we would like you to investigate and complete a suitable SAE.

Similarly if, at the 90 Day data collection, a patient is recorded as having had an event since discharge that has hospitalised them but no corresponding SAE exists, an e-mail message will be sent.

Forthcoming Change to Paperwork

In response to a specific request from our MREC, we have updated our PISs and consent forms to comply with current legal terminology ("consent" instead of "assent"). We have added a PIS for Independent Physicians. We have also included, in both PISs and the protocol, reference to the Office of National Statistics, or equivalent organisations internationally, to allow further information to be accessed for Follow Up. Formal notification of an implementation date for these will follow. We are currently waiting for regulatory approval.

World Stroke Conference

Reminder: ENOS and the STICH2 trial are jointly hosting a stand in Vienna at the World Stroke Conference. Do come and visit our stand if you are attending the conference.

Tip of the month

Please ensure that second CT scans are reported correctly on the Hospital Event Form. "Second CTs" refers to those scans undertaken on day 7, +/- 2 days as part of the ENOS trial, and only if the baseline scan was done before randomisation. Reports and images of all other routine clinical scans up to day 9 are still required, but not reported on, in any of the ENOS data collection forms.

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

- **SOPs:** Recording CT MR report data at day 7 v1.0, Recording SAE/SUSAR sponsor SOP v1.0, Protocol violations v1.2
- Protocol violation form v1.2

All forms can be downloaded from the website:

<https://www.nottingham.ac.uk/stroke-medicine/enos/jevpybki.htm>

**ENOS now has 69 centres in 13 countries.
More centres are welcome.**