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ENOS NEWS

Recruitment to 30 Apr

1784

International	**688**
Australia	**8**
Box Hill, Melbourne	*8*
Canberra	*0*
Canada	**33**
Cape Breton	*1*
Halifax (NC)	*32*
China	**103**
Tian Tan (NC)	*16*
Wenzhou	*87*
Egypt	**8**
Ain Shams Uni (NC)	*8*
Hong Kong	**4**
India	**67**
AIIMS (NC)	*22*
Armed For Med Coll	*1*
Ludhiana, CMC	*33*
Lilavati, LKMM	*11*
Malaysia	**8**
Univer Sains Mlya (NC)	*8*
New Zealand	**43**
Dunedin	*36*
Hawkes Bay (NC)	*3*
Hutt Hospital	*3*
Auckland	*1*
Philippines	**16**
Poland	**104**
Inst Psyc & Neur (NC)	*94*
Military Med Acad	*9*
Hospital Sandomierz	*1*
Republic of Ireland	**4**
Dublin, Tallaght (NC)	*4*
Romania	**73**
Clin Hosp, Oradea	*23*
Fogolyan Kristof Sftu	*23*
Mures County (NC)	*27*
Singapore	**155**
Singapore General	*155*
Spain	**7**
Hospital La Paz (NC)	*1*
Tarragona	*6*
Sri Lanka	**55**
South Colombo	*13*
Univ of Kelaniya (NC)	*42*

Newsletter for the Efficacy in Nitric Oxide Stroke Trial

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Serious Adverse Events

by Associate Professor Nikola Sprigg & Professor Daniel Berecki Independent SAE Adjudicators

Reporting of serious adverse events (SAEs) is an important aspect in all clinical trials and ENOS investigators have a responsibility to do so in a timely and detailed manner. We appreciate that all investigators are busy and so attempt to keep documentation to a minimum, but we do need to ensure that a minimum standard of information is provided. The following tips are aimed at improving the reporting process:

1) Is it a SERIOUS adverse event?

Remember, to be classified as such it must be a *new* event that either: results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, or results in a congenital anomaly/birth defect. For example; a urinary tract infection in an already hospitalised patient is not an SAE unless it is life threatening or prolongs the hospital stay by delaying discharge. Similarly, syncope or a fall is not an SAE unless it results in hospitalisation, prolongation of hospital stay or significant disability.

2) What was the relationship to treatment and potential causality?

Investigators must consider whether the SAE happened before, during or after treatment. An SAE occurring during or shortly after treatment should not usually be classified as 'Definitely not' or 'Definitely' as it is usually impossible to assign a definite relationship between the treatment and SAE.

3) Please provide enough information and clinical details.

Death in itself is not an SAE; the cause of death is the SAE whilst death is the outcome. Investigators need to provide enough information about the cause of death and evidence for it e.g. patient deteriorated, got pneumonia (clinical signs, chest x-ray, blood tests) and then died. Information should be entered on the website rather than be faxed to the ENOS office as the adjudication is done on-line. 'Death unattended' should only be used if the patient is found to have died and no cause is known. Investigators should seek information from other sources (GP, other hospital notes, autopsy report, death certificate) as necessary.

4) Headache.

Headache on the GTN patch is not an SAE unless it causes any of the above (e.g. delay in discharge, hospital re-admission). Headache is recorded on the day 7 form so should be documented there.

5) Is the event expected?

A SUSAR (suspected, unexpected serious adverse reaction) only occurs when the event is UNEXPECTED. For example, if a recovered stroke patient suddenly dies due to pulmonary embolism resulting from an unrecognized deep vein thrombosis of a leg, this is an unexpected death for the relatives (and maybe for the doctors also), but it should not be coded as unexpected, as pulmonary embolism is an expected adverse event in stroke patients. The majority of SAEs (pneumonia, cardiac events, falls) are expected events in stroke patients. If you think you have a SUSAR, please contact ENOS office if possible before ticking the SUSAR box on SAE form.

If you have any questions about SAEs, please do not hesitate to contact the ENOS office for advice.

ENOS now has 144 centres in 18 countries. More centres are welcome.

MRC Medical Research Council
The STROKE Association
The University of Nottingham

UK	1096
Aberdeen	76
Antrim Area Hospital, NI	5
Arrowe Park, Wirral	2
Barnsley	22
Blackpool Victoria	37
Borders Melrose	3
Charing Cross, London	1
Chesterfield Royal	22
Countess of Chester	7
Cumberland Infirm, Carlisle	1
Darlington/Bishp Auckland	72
Derby Hospitals	45
Diana Princess, Grimsby	5
Doncaster	20
Edinburgh Royal	7
Edinburgh Western	19
Fairfield General, Bury	12
Glasgow Royal Infirmary	14
Harrogate District	10
James Cook, Middlesbrgh	10
James Paget, Gt Yarmouth	2
John Radcliffe, Oxford	4
Kings College London	4
Leeds General Infirmary	11
Leicester General	7
Lincoln County	70
Macclesfield DGH	19
Monklands Glasgow	22
Musgrove Park, Taunton	2
New Cross Wolverhmptn	4
Newark Hospital	3
Newham General	29
Ninewells, Dundee	1
Northampton General	3
Northwick Park, London	7
Nottingham City	199
Nottingham QMC	23
Pilgrim Boston	47
Rochdale Infirmary	6
Royal Blackburn	1
Royal Cornwall	2
Royal Devon & Exeter	18
Royal Hallams Sheffield	1
Royal Lancaster	7
Royal Liverpool	3
Royal Preston	13
Royal United, Bath	1
Royal Victoria, Newcastle	4
Scarborough	7
Scunthorpe	2
Sherwood Forest Hospitals	7
Solihull Hospital	4
Southport & Ormskirk	1
St Marys Isle of Wight	2
St Richards, Chichester	1
Staffordshire General	1
Stockport Stepping Hill	20
Stobhill Glasgow	4
Stoke-on-Trent, Royal Inf	34
The Royal London	8
The Ulster Hospital	1
Torbay	15
University Hosp, Aintree	12
University Hosp, Coventry	3
University Hosp, Bristol	6
Victoria Hosp Kirkcaldy Fife	29
Watford General	16
West Cumberand Hosp.	1
Western Infirmary, Glasgow	2
Yeovil District Hospital	11
York Hospital	5
Ysbyty Gwynned, Bangor	1

Congratulations to....

- Holly Maguire at Stoke on Trent, UK for recruiting 3 patients in February.
- Six centres for winning the prize of a hamper for the ward for recruiting 3 patients in March: Barnsley Hospital, Lincoln County Hospital, Northwick Park, University Hospitals Bristol, UK; Lilavati Hospital, India and Mures County Hospital, Romania.
- All centres for recruiting **49** patients in March 2010 and **38** patients in April 2010. We need to recruit at least **45** patients a month to achieve our target.
- St Richards Hospital, Chichester for recruiting their first patient within 7 days of site initiation and for recruiting the patient in the first 12 hours after stroke.
- James Paget Hospital, Great Yarmouth, Royal United Hospitals, Bath, Royal Blackburn Hospitals, Arrowe Park, Wirral, Charing Cross Hospital UK for recruiting their first ENOS patients.
- Mures County Emergency Hospital, Romania, Stoke on Trent and Bishop Auckland Hospital UK for being the Highest Recruiting Centres in the last 90 Days.

*** New Recruitment offer: From May 2010, the centre recruiting the highest number of patients each month will be "Centre of the Month" and will receive a £100 bonus fund to be used at the centre's discretion (e.g. conference, hamper, other request) ***

India and Sri Lanka Investigator Meetings

An ENOS Investigator Meeting was held at the Vth National Congress of Indian Stroke Association and International Stroke Conference 2010 in Delhi on 13 March, attended by Kameshwar Prasad, Kamal Gulati, Mukesh Sriwastva, Philip Bath, Sharon Ellender and colleagues. There were many existing Indian Centres in attendance and some potential new centres. Philip Bath travelled on to meet with Prof Asita de Silva, Nirmala Wijekoon and colleagues in Columbo, Sri Lanka and hosted an Investigator Meeting with them.

Professor Asita de Silva
National Coordinator, Sri Lanka

Lilavati team: Dr Vinay Chauhan, Consultant Neurologist, Dr Sweta Adatia, Senior Resident in Neurology, Dr Gaurav Bansode, Junior Resident in Neurology, Sister Rita & Sister Mary Senior Nursing Staff

Tips of the month

- The **Day 7 form** should be completed 24 hours after the seventh treatment patch has been applied.
- If UK patients are expected to move during the 7-day treatment phase to a non-ENOS hospital, **do not** recruit them into the trial. If patients are expected to move locally to a non-ENOS hospital after the first 7 days, they **can** be recruited to the trial. In this case, the Hospital Event Form should be completed when the patient leaves the non-ENOS hospital.
- For **UK patients** that move, the recruiting centre will receive £27 for recruitment and the second centre will receive £18 for data collection and follow up. NIHR SRN will advise on how accruals will be assigned.
- **Temperature Monitoring Logs**: Please keep temperature monitoring logs for the GTN ward stock as per your local policy and retain a copy in your site file.
- **Faxes:** Please do not fax Baseline Form, Day 7, Hospital Event and SAE forms. Data entered online does not need to be faxed. Faxes we need are: Patient details, Consent form, OMRON BP sheet, Drug chart, CT report and Carotid report (if done).
- **Follow Ups:** Please do not recruit patients who will not provide contact details and who cannot be followed up at 90 days.
- **Patient Details** and consent forms should be stored separately from the patient's trial file, to ensure that identifiable data and clinical data are kept separate.

Staff change

- Tanya Payne returns from maternity leave to the role of UK Centre Coordinator on 17 May. Her contact details are Tel: 0115 823 0286 and Email: Tanya.Payne@nottingham.ac.uk. Our thanks go to Lynn Stokes for providing valuable cover in her absence and some of you will continue to liaise with Lynn on the PODCAST trial: www.podcast-trial.org. Email: Lynn.stokes@nottingham.ac.uk.

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

- Powerpoint presentation, Training v1.0, 21 Jan 2010
- MREC approval letter, 12 Feb 2010 • Human Tissue Act Licence, 24 Aug 2006
- ENOS UK Teleconference Workshop minutes, 27 Jan 2010
- Substantial amendment form, 9 Jul 2007