ISRCTN99414122 Feb 12, Issue 64

ENOS NEWS



Recruitment to 29 Feb '12

2861

Australia	8
Canada	33
Cape Breton	1
Halifax (NC)	32
China	103
Tian Tan (NC)	16
Wenzhou	87
Denmark	<u>4</u> 4
Uni of Copenhagen (NC)	
Egypt	95
Ain Shams Uni (NC)	9
Al Zahraa Hospital	23
Assiut Univ Hospital	54
Menoufiya Uni	9
Georgia	14
Barnovi City Hospital	4
Hospital War Veterans (NC)	10
Hong Kong	4
India	125
AIIMS (NC)	26
Armed For Med Coll	1
Christian Med Coll, Ludhiana	60
JIPMER	16
Lilavati, LKMM	17
Shree Krishna	5
	18
Italy	
University Perugia (NC)	15
Hospital Maggiore Policlinico	3
Malaysia	14
University Sains Mlya (NC)	8
Sarawak, Kuching	6
New Zealand	<u>60</u>
Auckland	1
Dunedin	53
Hawkes Bay (NC)	3
Hutt Hospital	3
Philippines	16
Poland	117
Hospital Sandomierz	6
Inst Psyc & Neur (NC)	102
Military Med Acad	9
Republic of Ireland	7
Dublin, Tallaght (NC)	. 7
Romania	162
Fogolyan Kristof Sftu	38
	72
Mures County (NC)	52
Spitalul Clinic, Oradea	
Singapore	<u>155</u>
Spain	<u>8</u>
Sri Lanka	88
South Colombo	30
Uni of Kelaniya (NC)	58

Newsletter for the Efficacy in Nitric Oxide Stroke Trial

Time to Randomisation Survey

Thanks to everyone who has completed the survey so far. Initial feedback is as follows:

- 96% of investigators agree that it is important to randomise ENOS patients early in the 48-hour time window.
- 64% of investigators think the protocol should not be changed to force early recruitment but agree with raising awareness.
- 73% of investigators are aware that patients can be enrolled to ENOS after thromboylsis (or even before if feasible).
- Suggestions to improve early recruitment were: ensure that local paramedics are informed and aware of the ENOS trial; increase weekend cover; and contact relatives immediately after admission.

Sickness or maternity leave

Clarification has been received from the Sponsor regarding sickness or maternity leave of the Principal Investigator.

The signature/delegation log should always show a nominated deputy (or two) for the PI to cover absences such as sickness and holiday so that recruitment does not have to stop and that someone is available to assess SAEs for causality and relatedness to the IMP.

Longer planned absences such as maternity leave, or illness that is likely to become longer term, would involve the deputy stepping up as official PI.

Tips of the month

- If, occasionally, blood pressure readings are missing for days 2 to 7, the Day 7 form can be left blank (do not enter a zero) for these fields online and submitted. Please note that BP readings 1-2 hours post patch placement are mandatory. But other BP readings are equally important.
- Please do not fax SAE forms or any form that you enter online. We need faxed documents for patient contact details, consent form, OMRON BP sheet, drug chart, CT report and carotid report (if done).
- If submitting a data correction form on SAEs, please include the SAE number (shown on the website once the SAE has been submitted).

ENOS now has 150 recruiting centres in 19 countries.

More centres are still welcome.









UK	<u> 1725</u>
Aberdeen	96
Antrim Area Hospital, NI	12
Arrowe Park, Wirral	6
Barnsley	47
Blackpool Victoria	42
Bradford Royal Infirmary	6
Charing Cross, London	15
Chesterfield Royal	32
Darlington/Bishop Auckland	97
Derby Hospitals	58
Diana Princess, Grimsby	7
Doncaster	35
Edinburgh Royal	7
Edinburgh Western	19
Fairfield General, Bury	16
Glasgow Royal Infirmary	25
Harrogate District	11
James Cook, Middlesborough	32
John Radcliffe, Oxford	17
Kings College London	6
Leeds General Infirmary	14
Leicester Royal Infirmary	19
Lincoln County	117
Macclesfield DGH	23
Monklands Glasgow	28
Musgrove Park, Taunton	14
New Cross Wolverhmptn	16
Newham General	29
Ninewells, Dundee	8
Norfolk & Norwich Uni Hosp	5
North Tees and Hartlepool	8
Northampton General	5
Northwick Park, London	64
Nottingham City	246
Pilgrim Boston Portsmouth Hospitals	71
Queens Medical Centre, Nottm	5 23
Rochdale Infirmary	23 6
Rotherham General Hospital	6
Royal Devon & Exeter	23
Royal Lancaster Infirmary	23 9
Royal Preston	13
Royal Victoria Inf, Newcastle	30
Salford Royal	10
Scarborough General Hospital	7
Sherwood Forest Hospitals	13
Shrewsbury & Telford	8
Solihull Hospital	6
St Richards, Chichester	14
Stockport Stepping Hill	22
Stobhill Hospital, Glasgow	5
The Royal Bournemouth	6
The Royal Inf, Stoke-on-Trent	63
The Royal London Hospital	12
Torbay District General Hospita	
University Hospital, Aintree	14
University Hospital, Coventry	5
University Hospitals, Bristol	7
Victoria Hosp Kirkcaldy Fife	44
Wansbeck and N Tyneside	7
Watford General Hospital	35
Western Infirmary, Glasgow	10
Whiston Hospital, Merseyside	6
Yeovil District Hospital	11
York Hospital	12

Please note that due to limited space, only centres that have recruited at least 5 patients will show on this list.







- West Suffolk Hospitals, Bury St Edmunds, UK; Lister Hospital, Stevenage, UK and Broomsfield Hospital, Chelmsford, UK for recruiting their first ENOS patients.
- All centres for recruiting the highest ever patients per month in January and February at 72 each month!
- Northwick Park, Harrow, UK; Al Zahraa Hospital, Cairo, Egypt; Mures County Emergency Hospital, Targu-Mures, Romania; James Cook University Hospital, Middlesborough, UK for being the highest recruiting centres in the last 90 days, recruiting at least 8 patients in 90 days.

SAES

ENOS has a low SAE rate (24%) for a 90 day acute stroke trial including ICH patients, and it is especially low overseas. Please ensure that you report all SAEs from randomisation to the 90 day Follow Up.

New centres

Welcome to the new centre in Georgia, at the War Veterans Hospital in Tblisi. They have randomised 10 patients, since their first one on 3 November 2011.



ENOS team: Tuina Kherkheulidze, Maia Beridze, Laura Kalichenko, David Eliauri, Tamar Kiladze, Marina Alpaidze, Maia Samkharadze.

And to South London Healthcare NHS Trust. in London UK.

Filomena Gomes (PhD student), Enock Khoromana (Research Coordinator), Galina Lohvin (Stroke SHO), Denisa Tryznova (Stroke SHO). Dr Piechowaaski Bart (PI), Dr Deborah Ramsey (Consultant).



Recently uploaded forms

- Patient pack v1.4
- SAE form v2.11, 5 July 2011
- List of "expected" SAEs, v1.5, 5 July 2011
- ENOS contact list, v2.2, 30 January 2012
- MREC Approval Letter, 20 January 2012 and 26 October 2011
- WPD Collecting and Freezing Blood samples v1.2, 24 February 2012
- Substantial amendment application to add new centres, 14 Dec 2011.