ISRCTN99414122 Jun 12, Issue 66

# **ENOS NEWS**



#### Recruitment to 30 Jun '12

3104

Australia	8
Canada	33
Cape Breton	1
Halifax (NC)	32
China	103
Tian Tan (NC)	16
Wenzhou	87
Denmark	9
Herlev Hospital	2
Uni of Copenhagen (NC)	7
Egypt	116
Ain Shams Uni (NC)	9
Al Zahraa Hospital	29
Assuit Univ Hospital	69
Menoufiya Uni	9
Georgia	25
Barnovi City Hospital	5
Hospital War Veterans (NC)	20
Hong Kong	4
India	143
AIIMS (NC)	29
Armed For Med Coll	1
Army Hospital, R&R	1
Christian Med Coll, Ludhiana	60
JIPMER	18
Lilavati, LKMM	17
Shree Krishna	7
SMS Medical College	10
Italy	22
University Perugia (NC)	19
Hospital Maggiore Policlinico	3
Malaysia	14
University Sains Mlya (NC)	8
Sarawak, Kuching	6
New Zealand	64
Auckland	1
Dunedin	57
Hawkes Bay (NC)	3
Hutt Hospital	3
Philippines	16
Poland	118
Hospital Sandomierz	6
Inst Psyc & Neur (NC)	103
Military Med Acad	9
Republic of Ireland	<u>8</u>
Dublin, Tallaght (NC)	8
Romania	184
Fogolyan Kristof Sftu	39
Mures County (NC)	93
Spitalul Clinic, Oradea	52
Singapore	<u>155</u>
Spain	8
Sri Lanka	93
South Colombo	32
Uni of Kelaniya (NC)	61

#### **Newsletter for the Efficacy in Nitric Oxide Stroke Trial**

Web: <u>www.enos.ac.uk</u> <u>Email: enos@nottingham.ac.uk</u> <u>Tel: +44 (0)115 823 1770</u> ENOS is on Twitter – please follow us on @enostrial

#### **ENOS Update**

Congratulations for all the hard work you have done to help ENOS recruit more than 3,000 patients. This is a fantastic achievement and makes us one of the largest ever trials in acute stroke (after CAST, IST, SAINT and IST-3). The next target is 3,500 (to fulfil the MRC grant target) although we should be able to make 4,000 by next summer if we can all maintain the current rate of recruitment (we have regulatory approvals up to 5,000).

#### **The RIGHT Trial**

As some of you may know, we have recently completed a small randomised controlled trial (called RIGHT) of transdermal glyceryl trinitrate patches or control in 41 (of an intended 80) patients with ultra-acute presumed stroke. The median time to recruitment was 50 minutes from stroke onset. Screening, consent, treatment and measurements were all done by paramedics in the ambulance. Of the 41 patients, 80% had a stroke. This trial showed that GTN was feasible and safe to administer (no excess in SAEs), and lowered blood pressure at 2 hours (the primary outcome). We will present the results of the trial at the forthcoming International Society of Hypertension and World Stroke Conference meetings, are busy writing up the results for publication, and are submitting shortly for a larger multicentre trial, RIGHT-2. Once written up, we will pass on the full results of RIGHT.

Further information on RIGHT is at: http://www.right-trial.org/

On the basis of the safety data from RIGHT, we urge you to enrol patients into ENOS as soon as they present to hospital (in the same way that you randomised, or treat with thrombolysis immediately on arrival). So far, ENOS has recruited patients over a 48 hour timeframe after stroke, with the majority after the hyperacute period and many in the second day. We now need far more patients treated in the first few hours after stroke if ENOS is going to inform hyperacute stroke clinical practice, and believe the data from RIGHT support this strategy. So please enrol very early after stroke.

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Philip Bath BSc MB BS MD FRCPath FRCP FESO Stroke Association Professor of Stroke Medicine Chief Investigator: ENOS NIHR Senior Investigator

**ENOS** now has 155 recruiting centres in 19 countries.

More centres are still welcome.







UK	2009
Aberdeen	100
Antrim Area Hospital, NI	12
Arrowe Park, Wirral	6
Barnsley	51
Blackpool Victoria Bradford Royal Infirmary	42 7
Bucks Healthcare Trust	7
Charing Cross, London	18
Chesterfield Royal	34
Darlington/Bishop Auckland	102
Derby Hospitals	61
Diana Princess, Grimsby Doncaster	9 37
East Surrey Hospital	6
Edinburgh Royal	7
Edinburgh Western	19
Fairfield General, Bury	17
Glasgow Royal Infirmary	25
Harrogate District James Cook, Middlesborough	11 36
John Radcliffe, Oxford	20
Kings College London	6
Leeds General Infirmary	14
Leicester Royal Infirmary	20
Lincoln County	128
Lister Hospital Macclesfield DGH	5 24
Monklands Glasgow	29
Musgrove Park, Taunton	19
New Cross Wolverhampton	16
New Queen Eliz, Birmingham	12
Newham General	29
Ninewells, Dundee Norfolk & Norwich Uni Hosp	10
North Tees and Hartlepool	5 10
Northampton General	6
Northwick Park, London	86
Nottingham City	259
Pilgrim Boston	76
Portsmouth Hospitals Princess Alexandra, Harlow	5 6
Queen Eliz Hosp, Gateshead	11
Queens Medical Centre, Nottm	
Rochdale Infirmary	6
Rotherham General Hospital	6
Royal Devon & Exeter Royal Lancaster Infirmary	24 9
Royal Liverpool University	6
Royal Preston	13
Royal Victoria Inf, Newcastle	31
Salford Royal	16
Scarborough General Hospital	
Sherwood Forest Hospitals Shrewsbury & Telford	14 8
Solihull Hospital	6
St Richards, Chichester	20
Stockport Stepping Hill	23
Stobhill Hospital, Glasgow	5
The Royal Bournemouth	6
The Royal Inf, Stoke-on-Trent	64
The Royal London Hospital Torbay District General Hospita	12 al 34
University College London Hos	
University Hospital, Coventry	5
University Hospital, Aintree	15
University Hospital, Coventry	5
University Hospitals, Bristol	7
Victoria Hosp Kirkcaldy Fife Wansbeck and N Tyneside	46 8
Watford General Hospital	36
Western Infirmary, Glasgow	13
Whiston Hospital, Merseyside	7
Worthing Hospital	8
Yeovil District Hospital York Hospital	11 14
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Please note that due to limited space, only centres that have recruited at least 5 patients will show on this list.

## 







- Army Hospital, New Delhi, India and South London Healthcare Trust, London, UK for recruiting their first ENOS patient.
- Northwick Park for recruiting 19 patients in the last 90 days; Mures County Emergency Hospital, Targu-Mures, Romania for recruiting 10 patients; SMS Medical College, Jaipur, India for recruiting 9 patients in the last 90 days.
- Prizes awarded at ESC: Copenhagen, Denmark for recruiting their first five ENOS patients. Warsaw, Poland; Bishop Auckland UK and Lincoln UK for recruiting 100 ENOS patients during the trial. A hamper has been sent to these centres. ENOS stand and meeting pictures from ESC are below.







## **ENOS Data Monitoring Committee**

The independent ENOS Data Monitoring Committee (DMC) have recommended that the trial should continue as is. Their report is on the ENOS website. Please note that they make two recommendations:

- 1. They urge investigators to include patients as soon after stroke onset as possible.
- 2. They ask us to continue our efforts to maintain adherence to allocated treatment, especially in the 'stop versus continue' arm of the trial.

Details on the RIGHT trial have already been mentioned on page 1. In respect of maintaining adherence, it is vital that patients are maintained on whatever treatment they are randomised to unless an over-riding clinical reason suggests otherwise. So, patients randomised to:

- GTN should receive GTN daily for 7 days
- No GTN should have no GTN for 7 days
- Continue pre-stroke antihypertensive therapy should receive all their prestroke antihypertensives daily for 7 days
- Stop pre-stroke antihypertensive therapy should receive none of their prestroke antihypertensives for 7 days

If we follow the DMC recommendations then we will maximise the quality of the trial and its relevance to daily clinical stroke practice.

## ip of the month

On the baseline form, "date and time of randomisation" should be the time at which the form is entered online, rather than the time that the patient gave consent. Please enter the data as soon as possible after taking consent (even a 30 minute delay could result in a protocol violation). This is important as we will analyse outcomes by time to randomisation.

#### Recently uploaded forms

- WPD, Protocol violations and deviations, v1.6, 1 February 2011
- WPD, List of WPDs, v1.1, 10 May 2012
- WPD, Transferring CT or MRI to the Coordinating Centre, v1.3, February 2012
- WPD, Continue/stop v1.1, 4 April 2012
- Minutes, UK and International Teleconference Workshops, May 2011
- MREC Amendment Request, 5 April 2012
- MREC Approval Letter, 25 April 2012