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Oct 09, Issue 50

ENOS NEWS

The Newsletter for the Efficacy in Nitric Oxide Stroke Trial
Web: www.enos.ac.uk Email: enos@nottingham.ac.uk

Recruitment to 31 Oct	
International	**621**
Australia	**8**
Box Hill, Melbourne	*8*
Canberra	*0*
Canada	**32**
Cape Breton	*1*
Halifax (NC)	*31*
China	**103**
Tian Tan (NC)	*16*
Wenzhou	*87*
Egypt	**4**
Ain Shams Uni (NC)	*4*
Hong Kong	**4**
India	**55**
AIIMS (NC)	*21*
Armed For Med Coll	*1*
Ludhiana, CMC	*25*
Lilavati, LKMM	*8*
Malaysia	**8**
Univer Sains Mlya (NC)	*8*
New Zealand	**43**
Auckland	*1*
Dunedin	*36*
Hawkes Bay (NC)	*3*
Hutt Hospital	*3*
Philippines	**16**
Poland	**100**
Inst Psyc & Neur (NC)	*90*
Military Med Acad	*9*
Hospital Sandomierz	*1*
Republic of Ireland	**1**
Dublin, Tallaght (NC)	*1*
Romania	**39**
Clin Hosp, Oradea	*14*
Fogolyan Kristof Sftu	*14*
Mures County (NC)	*11*
Singapore	**155**
Singapore General	*155*
Spain	**4**
Hospital La Paz (NC)	*1*
Tarragona	*3*
Sri Lanka	**49**
South Colombo	*9*
Univ of Kelaniya (NC)	*40*

Patients moving centres

The ongoing reorganisation of stroke services in the UK, with some hospitals becoming an acute and/or comprehensive centre and others focussing on rehabilitation, means that some patients will move hospital during their involvement with ENOS, either during or after the treatment phase (which lasts 7 days). We have drafted some procedures (which aim to address research governance and confidentiality issues) that should be adopted if patients move sites during the ENOS trial. There is a draft guideline document on the ENOS website, which is likely to be reviewed again as we refine practice, but this give some guidance:
https://www.nottingham.ac.uk/stroke-medicine/enos/EnosWpdPatientsMovingSitesV11.pdf

Changes in blood pressure and outcomes in acute stroke

We have performed a meta-regression analysis of 37 randomised controlled trials of interventions that would be expected, on pharmacological grounds, to alter BP in 9008 patients with acute stroke.[1] The results revealed a U-shaped relationship between blood pressure changes and outcome; with the lowest risk of death or combined death or dependency at the end of follow-up in patients with blood pressure reductions ranging between 8-15 mmHg. Although large falls or increase in blood pressure were associated with a higher risk of poor outcomes, modest reductions could reduce death and combined death or dependency, although confidence intervals were wide and compatible with an overall benefit or hazard. The results justify the testing of whether lowering BP is beneficial in improving functional outcome, as we are doing in ENOS.

Chamila M Geeganage and Philip MW Bath

Paper can be found at: http://hyper.ahajournals.org/cgi/content/full/54/4/775

References

1.Geeganage CM, Bath PM. Relationship between therapeutic changes in blood pressure and outcomes in acute stroke. A metaregression. *Hypertension*. 2009

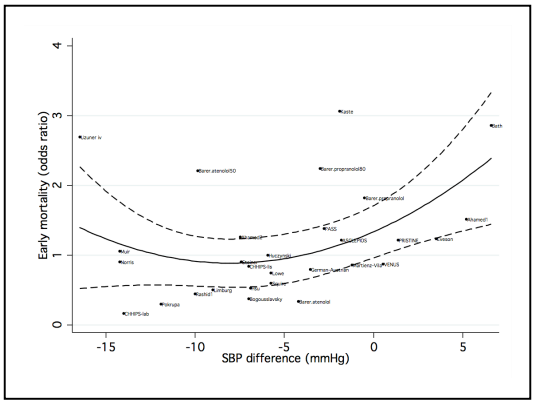

Figure 3. Relationship between death within 1 month and on-treatment systolic blood pressure difference (active minus control)

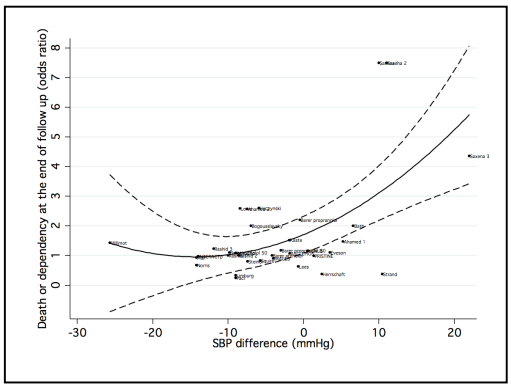

Figure 5. Relationship between death or dependency at end of follow up and on-treatment systolic blood pressure difference (active minus control)

MRC Medical Research Council
The STROKE Association
The University of Nottingham

UK	906
Aberdeen	*71*
Antrim Area Hospital, NI	*4*
Barnsley	*14*
Blackpool Victoria	*32*
Borders Melrose	*3*
Chesterfield Royal	*15*
Countess of Chester	*7*
Cumberland Infirm, Carlisle	*1*
Darlington/Bishp Auckland	*62*
Derby Hospitals	*39*
Diana Princess, Grimsby	*4*
Doncaster	*16*
Edinburgh Royal	*7*
Edinburgh Western	*15*
Fairfield General, Bury	*12*
Glasgow Royal Infirmary	*12*
Harrogate District	*8*
James Cook, Middlesbrgh	*7*
John Radcliffe, Oxford	*4*
Kings College London	*4*
Leeds General Infirmary	*6*
Leicester General	*4*
Lincoln County	*59*
Macclesfield DGH	*12*
Monklands Glasgow	*21*
New Cross Wolverhmptn	*4*
Newark Hospital	*3*
Newham General	*29*
Ninewells, Dundee	*1*
Northampton General	*2*
Nottingham City	*186*
Pilgrim Boston	*38*
QMC Nottingham	*23*
Rochdale	*1*
Royal Devon & Exeter	*16*
Royal Hallams Sheffield	*1*
Royal Lancaster	*4*
Royal Liverpool Uni Hosp	*1*
Royal Preston	*11*
Scarborough	*6*
Scunthorpe	*2*
Sherwood Forest Hospitals	*7*
Southport & Ormskirk	*1*
St Marys Isle of Wight	*2*
Staffordshire General	*1*
Stockport Stepping Hill	*20*
Stobhill Glasgow	*3*
Stoke-on-Trent, Royal Inf	*23*
Royal London	*4*
Torbay	*11*
University Hosp, Aintree	*12*
University Hosp, Coventry	*3*
University Hosp, Bristol	*2*
Victoria Hosp Kirkcaldy Fife	*22*
Watford General	*12*
West Cumberand Hosp.	*1*
Western Infirmary, Glasgow	*2*
Yeovil District Hospital	*11*
York Hospital	*2*

Grand Total:

1,527

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Congratulations to....

- The Royal London Hospital, UK, Diana Princess of Wales Hospital, Grimsby, York Hospital, University Hospitals, Bristol, Rochdale Infirmary UK and Royal Liverpool University Hospital UK for recruiting their first ENOS patients.
- Christian Medical Centre, India for recruiting the fastest ever patient in 1 hour 15 minute from stroke onset to randomisation.
- All centres for recruiting 57 patients in September 2009 – the highest yet! – taking our average in the last 4 months to 50 patients (from 37).
- Romania for holding the top two positions on the list of Highest Recruiting Centres in the last 90 days.
- Lincoln County Hospital, UK for recruiting patient number 1,500.
- Poland for recruiting 100 ENOS patients.

Recruitment offer

Each centre that recruited 3 patients in the month of October will receive a hamper for the ward.
Well done to: Lilavati Hospital, Mumbai, India
Oradea, Romania
Antrim Area Hospital, UK
Derby Hospitals, UK
Chesterfield Hospital, UK
Torbay District General Hospital, UK

Tips of the month

- **SUSARs (Suspected Unexpected Serious Adverse Reaction)**: GTN is a very long established medication and a SUSAR in the context of the ENOS trial is very unlikely. We have prepared Standard Operating Procedures to guide you as to when a reaction may be a SUSAR and crucially, when it is not. **If in doubt, please call the ENOS Trial Office** urgently to discuss whether the SAE could be a SUSAR.

- **Follow Ups -** Please ensure the patient baseline details form is fully completed to ensure patients can be contacted promptly at 90 Days by the ENOS Follow-Up Coordinators.

- **OMRON time** - For all centres in UK and those around the world that are affected by the clock change, remember to change the time on your OMRON machines (for UK, clocks go back one hour from 25 October).

- **Definition of TIA** – For the trial purposes - the definition of TIA is 24 hours. We appreciate that some hospitals use 1 hour, but for consistency in the trial, please use 24 hours.

- **Carotid Doppler** – Please ensure it is clear that if a Carotid Doppler is performed and submitted only for the ENOS trial, or payment will not be made.

ENOS Teleconference Workshops

Many thanks to the 21 UK collaborators that participated in the ENOS teleconference workshop on 30 September. The minutes have been circulated to all UK Investigators and are also uploaded to the ENOS website. The next scheduled UK teleconference workshop is:

Wed 27 January 1.00 GMT UK Teleconference Workshop

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

- ENOS Trial Office contacts v1.7
- List of SAEs, v1.1
- Substantial amendment form, 6 August 2009, to add new UK centres
- UK and International Teleconference Minutes, Jun, July, Sep 2009
- Annual MREC Report, Oct 2008
- Insurance letter updated to include Georgia, 28 Sep 2009
- FAQ, v2.0
- Substantial amendment to add new UK centres – MHRA/MREC approval – Aug 09
- Patients moving centres v1.1

ENOS now has 125 centres in 18 countries. More centres are welcome.