ISRCTN99414122 Jul 13, Issue 71

ENOS NEWS



Recruitment to 31 Jul '13

3898

	_
Australia	8
Canada Cape Breton	<u>33</u> 1
Halifax (NC)	32
China	103
Denmark	17
Herlev Hospital	2
Hillerod Hospital	1
Uni of Copenhagen (NC)	14
Egypt	<u>133</u>
Ain Shams Uni (NC)	9
Al Zahraa Hospital Assuit Univ Hospital	31 84
Menoufiya Uni	9
Georgia	178
Barnovi City Hospital	7
Hospital War Veterans (NC)	30
Municipal Hospital	141
Greece	12
Larissa Univ Hospital (NC)	12
Hong Kong	<u>4</u>
India	157 31
AIIMS (NC) Christian Med Coll, Ludhiana	
JIPMER	20
Lilavati, LKMM	17
Shree Krishna	7
SMS Medical College	12
Italy	33
Hospital Maggiore Policlinico	5
University of L'Aquila	9
University Perugia (NC)	19
Malaysia	<u>14</u>
University Sains Mlya (NC)	8
Sarawak, Kuching	6 70
New Zealand Auckland	<u>70</u> 1
Dunedin	63
Hawkes Bay (NC)	3
Hutt Hospital	3
Norway	4
Aalesund Sjukhus	3
Oslo University Hospital	1
Philippines	16
Poland	123
Hospital Sandomierz Inst Psyc & Neur (NC)	6 108
Military Med Acad	9
Republic of Ireland	10
Dublin, Tallaght (NC)	10
Romania	214
Fogolyan Kristof Sftu	48
Mures County (NC)	114
Spitalul Clinic, Oradea	52
Singapore	<u> 155</u>
Spain	403
Sri Lanka South Colombo	103 38
Uni of Kelaniya (NC)	65
Sweden	12
Danderyd Hospital (NC)	9
Hassleholm Hospital	1
KSS Hospital, Skovde	1
SUS/Malmo Hospital	1
Turkey	14
Ankara Numune Edn Res Ho	
Ankara University	1
Gazi University	2 5 3
Istanbul University Selcuk University (NC)	2
OCICUR OTHERSILY (IVC)	3

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

INTERACT Trial Results

As you may know, the results of the large (2839 patients, 68% from China) INTERACT-2 trial of blood management (intensive versus guideline lowering) in hyperacute (<6 hours) intracerebral haemorrhage (ICH) was presented at the European Stroke Conference, and then published in the New England Journal of Medicine. The trial was neutral on its primary outcome (mRS>2) but with a strong trend to benefit with intensive BP lowering. Important secondary outcomes were either positive (shift analysis of mRS, Euro-QoL quality of life) or neutral with strong trends.

At present there are two ongoing trials assessing patients with hyperacute (ATACH-2 in USA) or acute (ENOS) ICH. We have considered what effect, if any, the INTERACT-2 results should have on ENOS recruitment of ICH patients. Since the trial was technically neutral (p=0.06), it will not fulfil the requirements for Level A/Class 1 evidence; hence, it can be argued that further data are required. Nevertheless, the results qualitatively fit in with many peoples' expectations and hope for the role of intensive BP lowering in ICH! The results, and a debate on them, can be found at:

http://www.medscape.com/viewarticle/804916?nlid=31583 326&src=wnl edit medn neur&uac=73919PG&spon=26

The planned 'Blood pressure in Acute Stroke Collaboration' (BASC) individual patient data meta-analysis of BP management in ICH will include data from INTERACT-2, and ICH patient data from CHHIPS, ENOS, IMAGES and SCAST etc. Hopefully, this much larger dataset will provide absolute clarity to the question of BP management in acute ICH.

The ENOS Data Monitoring Committee have reviewed the INTERACT-2 results in the context of ENOS and agree with the plan to continue recruitment of ICH patients into ENOS (see latest DMC letter on the documents website). Nevertheless, these seem powerful reasons to continue recruitment of ICH patients, including <6 hours of onset, into the remaining time that ENOS will run for.

So, please keep recruiting into ENOS, and include patients with ICH, including those presenting very early, and let's get the whole trial to 4000 patients!

ENOS now has 170 recruiting centres in 23 countries and the aim is to recruit at least 4,000 patients. Recruitment is ongoing to end of October, so please keep going.







UK	<u>2477</u>
Aberdeen Airedale NHS Trust	119 5
Antrim Area Hospital, NI	12
Arrowe Park, Wirral	7
Barnsley	69
Blackpool Victoria Bradford Royal Infirmary	50 8
Bucks Healthcare Trust	14
Charing Cross, London	23
Chesterfield Royal	38
City Hospitals, Sunderland Darlington/Bishop Auckland	6 113
Derby Hospitals	66
Diana Princess, Grimsby	9
Doncaster	45 14
East Surrey Hospital Edinburgh Royal	7
Edinburgh Western	19
Fairfield General, Bury	19
Glasgow Royal Infirmary Harrogate District	32 14
James Cook, Middlesborough	48
John Radcliffe, Oxford	23
Kings College London	8
Leeds General Infirmary	19 24
Leicester Royal Infirmary Lincoln County	170
Lister Hospital	7
Macclesfield DGH	36
Monklands Glasgow	33
Musgrove Park, Taunton New Cross Wolverhampton	24 25
New Queen Eliz, Birmingham	28
Newham General	29
Ninewells, Dundee	10
Norfolk & Norwich Uni Hosp North Tees and Hartlepool	5 21
Northampton General	7
Northwick Park, London	110
Nottingham City Pilgrim Boston	284 90
Pinderfields General Hospital	13
Portsmouth Hospitals	8
Princess Alexandra, Harlow	11
Queen Eliz Hosp, Gateshead Queens Medical Centre, Nottn	22
Rochdale Infirmary	6
Rotherham General Hospital	7
Royal Blackburn Hospitals	7
Royal Devon & Exeter Royal Lancaster Infirmary	25 9
Royal Liverpool University	9
Royal Preston	13
Royal Victoria Inf, Newcastle	43
Salford Royal Scarborough General Hospital	17 13
Sherwood Forest Hospitals	14
Shrewsbury & Telford	8
Solihull Hospital	6
South London Healthcare NHS St Richards, Chichester	S 22 25
Stockport Stepping Hill	23
Stobhill Hospital, Glasgow	5
The Royal Bournemouth	9
The Royal Inf, Stoke-on-Trent The Royal London Hospital	75 13
Torbay District General Hospit	
University College London Hos	sp 7
University Hospital, Coventry	5 15
University Hospital, Aintree University Hospital, Coventry	15 5
University Hospitals, Bristol	7
Victoria Hosp Kirkcaldy Fife	57
Wansbeck and N Tyneside	16
Watford General Hospital Western Infirmary, Glasgow	45 23
Whiston Hospital, Merseyside	8
Worthing Hospital	13
Yeovil District Hospital York Hospital	11 18
TOTA HOSpital	10

(Recruited at least 5 patients).

Congratulations to...



- Ankara Numune Education and Research Hospital, Turkey for recruiting the fastest ENOS patient in May in 3.29 hours and to Lincoln County Hospital, UK for recruiting four patients in 4 weeks in May. Both centres have been sent a chocolate hamper.
- Nottingham City Hospital, UK for recruiting the fastest ENOS patient in June in 2.8 hours and to Municipal Hospital, Tblisi Georgia for recruiting the most patients (5) in June. Both centres have been sent a hamper.
- Istanbul University, Turkey for recruiting patient number 3800. A bonus
 payment of £300 for use to attend the European Stroke Congress, Nice in May
 2014 will be made.
- Congratulations to Lincoln County Hospital, UK, Municipal Hospital, Georgia and Mures County Hospital, Romania for recruiting at least 5 patients in July (6, 10 and 7 patients respectively!). A bonus payment of £250 will be included in their next centre payment.
- RECRUITMENT COMPETITION: The centre that recruits five ENOS patients in August 2013 will receive £250 towards attending the ESC and ENOS results meeting in May 2014.
- Hampers and prizes for early recruitment and the most and earliest patients recruited every month are ongoing.

Congrats to Prof Ince and team in Turkey for recruiting ENOS patient 3800!

Sitting L to R: Prof MD Birsen İnce (Head of the team), Ass Prof MD Derya Uludüz. Standing from left to right: Şükriye Menkü (2nd year assistant-MD), Serap Kıvanç (stroke clinical secretary), Lokman Salbacak (outpatient clinical registration officer), Nilay Şimşek (stroke clinical nurse specialist)



ENOS Recruitment

Please continue to recruit to ENOS! We have approval for an extended end date to January 2014, so recruitment can carry on into October 2013 and Follow Ups will be complete by end of January. Recruitment will continue until we have at least 4000 patients with a primary outcome. The MREC approval letter/minor amendment for the extended date is on the website.

Tin of the month

A change has now been made on the ENOS baseline form to question D13. Previous wording was "Have you just given, or do you intend to give, tissue plasminogen activator (rt-PA) (alteplase) to this patient?". This now reads "Have you or do you intend to perform thrombolysis/thrombectomy on this patient?"

Please tick 'yes' for this question if a patient has intra-artareial reperfusion therapy (such as thrombectomy), whether or not they also have thrombolysis.

Recently uploaded documents

ENOS contacts, v2.4, 26 June 2013
Baseline form v3.5, 26 July 2013
MREC acknowledgement of minor amendment, 29 July 2013
Insurance renewal letters, 1 August 2014 onwards
DMC letter, 6 June 2013