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TARDIS NEWS

849

Recruitment at 31 July 2012

Aberdeen Royal Infirmary	14
Airdrie: Monklands	15
Ashford: William Harvey	5
Barnsley District Gen.	12
Barnstaple: North Devon D	2
Basildon University Hosp.	2
Basingstoke: Hampshire H(	6
Blackpool Victoria	1
Bristol, BRI,	2
Chesterfield Royal	15
Colchester General	15
Countess of Chester	31
Croydon, London	10
Dewsbury & District Hosp.	11
Dorset County Hosp.	1
Eastbourne General	15
Forth Valley, Larbert	5
Gateshead, Q.Elizabeth	10
Glasgow Royal Infirmary	8
James Paget, Gt Yarm	1
Kettering General Hosp.	1
King's College, London	60
King's Mill, Sutton in Ash.	16
Leeds General Infirmary	28
Lincoln County	1
Leicester, LRI,	8
Margate, QEQM	24
NHS Fife, Kirkcady/Dunf	4
North Staffs, Stoke	71
Nottingham Univ Hosp.	84
Pillgrim Hospital, Boston	1
Plymouth Hospitals	1
Princess Royal, H.Heath	4
Raigmore Hosp, Inverness	1
Rotherham Hospital	10
Royal Bournemouth	9
Royal Cornwall, Truro	17
Royal Derby Hosp	36
Royal Devon & Exeter	28
Royal Liverpool	7
Royal Preston	12
Royal Surrey, Guildford	10
Royal United Hosp,Bath	2
RVI, Newcastle	10
Sheffield Teach Hosps.	8
Southend University NHS.	5
Stockport, Stepping Hill	3
St Georges,London	77
St Peters Hospital, Chertse	8
The Calderdale Royal	23
The Ipswich Hospital	5
Torbay District Hospital	19
Univ.Hospital Aintree	33
Watford General	5
Wansbeck & N.Tyneside	5
Whitehaven/W.Cumb.Hosp	7
Whiston Hospital,Prescot	14
Yeovil District Hosp	11

Newsletter for the Triple Antiplatelets for Reducing Dependency after Ischaemic Stroke Trial

Web: *www.tardistrial.org* *Email: tardis@nottingham.ac.uk* *Tel: 0115 82 31770*

TARDIS is now on Twitter – please follow us on @tardistrial

Congratulations to….

St Peters Hospital, Chertsey and & Pilgrim Hospital, Boston for recruiting their first patients

******* **Exciting news** *******

As you are aware the 5-year main phase has been funded and we are pleased to announce that contracts have now been signed.
The new funding will take effect from 1 October 2012

Many thanks to all of you who contributed to the enormous achievement of recruiting 849 participants to-date, long may this continue.

With reference to the changes which will take place from 3rd September, please ensure that your new randomisation choices have been sent to us in good time.

Also please bear in mind that if we have not received a copy of your local R&D approval letter for the new protocol V1.3 and changes to consent forms and information sheets V1.5, then you will be unable to randomise any patients from 3rd September 2012.

Details of new trial staff and contact numbers have been updated overleaf as Margaret will be moving over to work on other trials. Tanya Payne will be the new Trial Co-ordinator as from 6th August 2012. the main trial office telephone and fax numbers have all been updated. Please can you send all general email enquiries directly to tardis@nottingham.ac.uk which can be accessed by all trial staff.

Payments to sites

We need to pay more sites for patient recruitment and reimburse travel expenses as soon as possible before the BHF funding expires.
To enable us to do this could we please ask you to check that you have faxed us copies of consent forms, patient contact details, anonymised radiology scan reports and drug chart, entered all follow-up visits on the website and further reportable events experienced by the patient right up until the Day 90 telephone call has been completed. We require copies of all radiology scans undertaken from onset to day 90 follow-up telephone call. All queries must also be resolved before payment can be made.

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Payments to sites continued....

For reimbursement of travel expenses we will require copies of either the signed expenses form paid directly to the trial participant, showing the full trial id/follow-up visit, or a copy of the taxi invoice showing the details of the participant. If these are not received by the beginning of November then we cannot guarantee reimbursement of these expenses.

Help,Tips, Clarifications

Current Protocol V1.2
At the time of randomisation all symptoms must be resolved if randomising a patient as a TIA, and ongoing if randomised to Stroke.
On the day of randomisation (Day 0), all participants must receive 300mg loading dose of aspirin and a minimum of 200mg dipyridamole. If randomised to triple (intensive) then 300mg clopidogrel must also be given. The doses of aspirin and clopidogrel are reduced to 75mg a day until the end of the treatment period. Dipyridamole is increased to 200mg twice a day.
Clopidogrel must not be given after onset of the randomising event, and prior to randomisation otherwise the participant is ineligible.
The actual antiplatelets given may change from 3/9/12 depending on your new randomisation choices, but the doses themselves will not change.

Could we please ask that you ensure all new events are reported as it is crucial they are recorded for the trial. At the moment our recurrent event rate is unexpectedly low. Please try and recruit within the first 12-24hrs of onset, to prevent recurrent events.

The new SAE/Outcomes CRF (V2.3). Has recently been circulated via email. Please use this version in place of the version on the website. This will shortly be updated.

Please enter any drop in Hbs as a Bleed Outcome. If there is no known cause then choose 'other bleed' from the category list and enter this in the comments box below. Once the results of any tests are received or a diagnosis is made, please update the event by sending a completed data correction form to the trial office, and please send corroborating paperwork evidence to us.

Any patients who have taken either dipyridamole or clopidogrel after onset of their latest event are not eligible for TARDIS.

Co-enrolment of patients into iPAM Stroke Intervention Trial (iSIT) can be made. This is a UKCRN Portfolio Study. Uses robotic arm therapy and is not a drug trial, Confirm in Newsletter. Further details of trial from b.bhakta@leeds.ac.uk

Patients with existing tumours have increased bleeding risk therefore patients should not be recruited

It is very important to continue the randomised trial treatment for the 28/30 day treatment period, unless new events clinically indicate this should be altered.

We require NHS number for all new participants. Please always enter this on the Patient Contact Details.