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TARDIS NEWS

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Recruitment at 31 Aug 2010

Aberdeen Royal Infirmary	3
Basingstoke	1
Blackpool Victoria	1
Chesterfield Royal	7
Countess of Chester	16
Dorset County	1
Glasgow RI	2
James Paget, Gt Yar	1
King's College, London	1
Leeds District General	2
Mayday, London	5
Monklands, Airdrie	5
North Staffs, Stoke	16
Nottingham	32
Plymouth	1
Princess Royal, H.Heath	1
Royal Cornwall, Truro	12
Royal Derby Hosp	12
Royal Devon & Exeter	7
Royal Liverpool	4
Royal Preston	2
Royal Surrey, Guildford	3
Southend	3
St Georges, London	21
Stepping Hill,Stockport	1
The Calderdale Royal	12
The Ipswich Hospital	3
The Royal Bournemouth	4
Torbay District Hospital	7
Univ.Hospital Aintree	2
West Cumberland, Whitehaven	6
Yeovil District Hosp	5

TARDIS Trial Office

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Newsletter for the Triple Anti-platelets for Reducing Dependency after Ischaemic Stroke Trial
Web: *www.tardistrial.org* *Email: tardis@nottingham.ac.uk*

Congratulations to…

- Basingstoke, Blackpool Victoria, Glasgow RI, Haywards Heath, Royal Bournemouth, Royal Liverpool & Stockport - for randomising their first TARDIS patients.

Welcome to…

- Bath, Gillingham, Inverness, Kettering, Rotherham & Wishaw - waiting to recruit their first patient.

Next TARDIS Teleconference

Friday, 1st October 2010 12:30 to 1:30pm
We will let you know by email of the freephone telephone number to ring.
Please do not ring outside the above times as we do get charged for this even though the teleconference may have finished.

Tips, clarifications

- Please see the new Flowchart (V1.4) on the website clarifying further the inclusion criteria of acceptable symptoms for 'motor weakness'.
- Please fax the consent forms, and patient details form to us within 2 days of taking consent.
- The NIHSS plus 2 x blood pressure/pulse readings need to be undertaken after written consent has been obtained by an approved medic, but before randomisation.
- Please use the SRN 1-page CV layout wherever possible. This should be recently signed and dated by the investigator, and must include their latest GCP training date.
- Nottingham Co-ordinating Centre staff must approve any new investigators prior to their commencement on the trial. Therefore please fax over the CV/GCP certificate plus the authorised amended signature(delegation) log to allow us to do this in accordance with GCP regulations.
- If investigators leave/stop working on the trial they must be signed off by the PI on the signature(delegation) log i.e. date left trial. Do not remove their CV/GCP from the Investigator Site File as they must be kept for monitor/audit purposes.
- It would help us immensely if investigators would please try and obtain a name/address/telephone number of someone other than the next of kin on the Patient Details form, especially if the next of kin actually lives with the recruit. It is important that our 90-day follow-up co-ordinator is able to contact the recruit at the scheduled date.

British Heart Foundation
The University of Nottingham

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Tips, clarifications... (continued)

- On the Baseline Form, the choice 'Inpatient' must only be chosen if the patient was already hospitalised PRIOR to their randomising event. They are not classed as an existing inpatient if admitted for the randomising event. (see Working Practice Document 004 on the website: http:www.tardistrial.org/jevpybki.htm)
- Data correction forms are only used to correct any information entered by investigators onto the website (i.e. eCRF). If the paper CRFs need correcting then the incorrect entry needs a line putting through it, the correct response ringed, and the investigator making the correction should initial and date against the correction, to comply with GCP regulations.
- If a patient has resolved limb weakness – (min 10mins duration, max 24hrs) even though the radiology result may show evidence of a stroke, they can be randomised as a TIA. You are randomising on the symptoms and not the result of the CT. The CT is to rule out haemorrhages and whether or not it shows a new infarct would not necessarily change the original diagnosis for the trial. Later when you complete the Hospital Event form the final diagnosis may then alter as a result of all evidence at that time.
- When communicating between hospital and Co-ordinating Centre (email, fax etc) please ensure that the full trial ID is quoted giving Centre Number (C999) Recruit ID (9999) Recruit initials (ZZZ) as per the example below:

  C999/9999/ZZZ

- The above also applies to any blood samples taken – they should be anonymised as above and include the date taken, visit date and sample name (serum/plasma/DNA).
- Patients must not be recruited if already taking clopidogrel.
- The recruit's trial id number needs adding to all consent forms after the patient is randomised. Please do this prior to copying and filing in the trial file and hospital notes.

Clopidogrel accountability

An accountability log needs completing for any clopidogrel dispensed, whether from pharmacy or straight from the ward/clinic stock. If a stock of clopidogrel has been dispensed to the ward (rather than a particular patient) then the investigator is responsible for completing a further log, once this is dispensed to a recruit. This must be kept in the Investigator Site File for audit/monitoring purposes.

Also a temperature log needs completing – check with your pharmacy regarding accep temperature range, as the drug will need replacing if temperature is logged outside th limits.

Hospital admission .... Or not.... that is the question!

Just to clarify that – for the purposes of the trial only – patients are only classed as being admitted to hospital if they are in the hospital overnight for their randomising event.
If the patient goes home from hospital the same day they arrived, whether this is through EAU, A&E or any other ward, then please enter details on the eCRF as if they were never admitted.

New member of staff

Welcome to Diane Havard who has recently joined the TARDIS team, working as joint Trial Co-ordinator with Margaret – she can be contacted on 0115 823 1773 and email: diane.havard@nottingham.ac.uk

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