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TARDIS NEWS

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

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Recruitment at 30 Apr 2010

Total number of patients recruited per centre

Aberdeen Royal Infirmary	1
Calderdale Royal	1
Chesterfield Royal	3
Countess of Chester	11
James Paget, Gt Yar	1
Leeds District General	1
Mayday, London	1
Monklands, Airdrie	2
North Staffs, Stoke	4
Nottingham	24
Plymouth	1
Royal Preston	1
Royal Cornwall, Truro	10
Royal Derby Hosp	9
Royal Devon & Exeter	2
Royal Surrey, Guildford	3
Southend	1
St Georges, London	10
The Ipswich Hospital	2
Torbay, Torquay	6
University Hospital Aintree	2
West Cumberland, Whitehaven	4
Yeovil District Hosp	2

TARDIS Trial Office

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Congratulations to…

- Aberdeen, Calderdale, Chesterfield, Chester, James Paget, Leeds, Mayday, Monklands, Stoke, Plymouth, Preston, Exeter, Guildford, Southend, St Georges, Ipswich, for randomising their first TARDIS patients.

Welcome to…

- Bournemouth, Dorchester, Brighton & Haywards Heath, Grimsby, Glasgow RI, Bristol and Liverpool Royal - all waiting to recruit their first patient.

Potential withdrawal of recruits from trial

Unfortunately some participants have requested to 'withdraw' from the trial early for various reasons.

It is unusual for a participant to withdraw totally from a trial. They may be happy to consent to telephone follow-ups rather than face-to-face visits at clinic. So please investigate further and let us know the outcome as soon as possible as to what patients actually mean by early withdrawal. But it is vital that the day 90 final follow-up is done by telephone otherwise all the previous involvement by the patient is wasted.

A new form will shortly be upload onto the TARDIS website for investigators to complete and fax back to Nottingham Co-ordinating Centre if a patient says they wish to withdraw. Until then, then please notify us immediately if you are aware of any impending withdrawals.

** Recommendation for gastro protection**

CLOPIDOGREL & PROTON PUMP INHIBITORS (PPI)

Guidelines support the use of PPIs to reduce the risk of gastro intestinal bleeding, in patients on dual or triple antiplatelet therapy.[1] However, after several observational studies reported that PPIs might reduce the effectiveness of clopidogrel, the Medicines and Healthcare Products Regulatory Agency (MHRA) and the European Medicines Agency (EMA) issued statements last year, discouraging the concomitant use of these medications.
Since then, several other studies have been published that question the class effect and the clinical significance of this drug interaction. The EMA has now issued a revised statement, and while discouraging the use of omeprazole and esomeprazole with clopidogrel, felt there was no evidence to extend the warning to other PPIs. (http://www.ema.europa.eu/humandocs/PDFs/EPAR/Plavix/17494810en.pdf. downloaded 10 May 2010)

So for participants recruited into the TARDIS study, any PPIs other than omeprazole or esomeprazole may be used for gastric protection, subject to local policy.

1. Bhatt DL, Scheiman J, Abraham NS, Antman EM, Chan FK, Furberg CD, et al. ACCF/ACG/AHA 2008 expert consensus document on reducing the gastrointestinal risks of antiplatelet therapy and NSAID use: a report of the American College of Cardiology Foundation Task Force on Clinical Expert Consensus Documents. Circulation. 2008 Oct 28;118(18):1894-909.

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Tips, clarifications

- The Hospital Events form, including the aetiology section, needs to be completed for **all strokes and TIAs**. This form is shortly to be updated to V1.3.
- CDs containing CT or MR images must not be posted to Nottingham unless encrypted. Once the upload facility is available on the website it will be possible to upload scans directly.
- Please remember to collect blood samples for platelet function and send to Nottingham using the prepaid Royal Mail boxes. These measurements are part of the main study. There is a Working Practice Document available on our website describing these samples.
- Please use the SRN 1-page CV layout wherever possible. This should be signed and dated by the investigator and include their latest GCP training date.
- Trial Loading Doses. Irrespective of what the recruit has taken prior to entering the trial, on the day of randomisation each recruit should receive the loading dose of aspirin 300mg, and if randomised to triple then also clopidogrel 300mg, as soon as possible after trial bloods are taken. Dipyridamole also commences on the same day, with one or two doses depending on the time of randomisation.
- Please be very precise when requesting required changes to your database entries, when faxing Data Corrections Forms. Please name the precise fields needing amendment and sign/date the form.
- SAEs/Outcomes - should have a 'began' time, even when this is unknown. In the latter case, the time should be estimated as a 'halfway' time, e.g. if just the date is known then midday should be chosen. If the investigator knows it happened within the last 18hrs of a given timepoint, then the time would be 9hrs prior to the given timepoint.
- Possible side effects of antiplatelets (i.e. dipyridamole headache). Most are not classed as SAEs and can be reported on the Day 7 and Day 35 follow-up forms where applicable, as AEs are not otherwise collected for the trial.
- On the Day 7 or Day 35 forms, if any fields from '1a Death' To '16a. Carotid Endarterectomy' are answered as 'Yes' then please complete the online Outcome/SAE form at the same time.
- Many Day 7 and Day 35 visits are being completed beyond the trial timeline – please try and undertake Day 7 within 1 day of actual due date, and Day 35 within 3 days of due date. Also please enter the data as soon as possible on the website. In the future, emails will be sent to investigators before and after the expected dates.

Next TARDIS Teleconference

Friday 18th June 2010 12:30 to 1:30pm
We will let you know by email of the freephone telephone number to ring.

Baseline scans

There appears to be some confusion over what constitutes a baseline scan. Scans can only be classed as baseline if they are undertaken prior to the date and time of randomisation. Any scans undertaken after that time are classed as 'Other Clinical Scans'.
If a patient diagnosed with a TIA is consented and randomised prior to being scanned, but later the same day has a CT or MR – the result of this goes into 'Other Clinical Scans' and is not reported as the baseline scan on the Day 7 form.
If a patient has been thrombolysed and has had 2 x scans prior to being randomised, then the later scan will be classed as the baseline scan.