

TARDIS NEWS

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Recruitment at
30 Apr 2011

Aberdeen Royal Infirmary	8
Barnsley District Gen.	2
Basildon University Hosp.	2
Basingstoke	4
Blackpool Victoria	1
Chesterfield Royal	11
Colchester General	2
Countess of Chester	26
Croydon, London	8
Dewsbury & District H.	2
Dorset County H.	1
Eastbourne General	3
Glasgow RI	4
James Paget, Gt Yarm	1
Kettering General	1
King's College, London	14
Leeds General Infirmary	13
Margate, QEQM	5
Monklands, Airdrie	9
North Staffs, Stoke	41
North Devon District H.	1
Nottingham Univ Hosp.	45
Plymouth Hospitals	1
Princess Royal, H.Heath	1
Royal Bournemouth	6
Royal Cornwall, Truro	17
Royal Derby Hosp	20
Royal Devon & Exeter	16
Royal Liverpool	7
Royal Preston	8
Royal Surrey, Guildford	8
Royal United H,Bath	1
Southend University NHS.	3
St Georges, London	37
Stepping Hill, Stockport	1
The Calderdale Royal	18
The Ipswich Hospital	4
Torbay District Hospital	14
Univ.Hospital Aintree	13
Watford General	1
West Cumberland, Whitehaven	7
Whiston Hospital,Prescot	2
Yeovil District Hosp	9

Newsletter for the Triple Anti-platelets for Reducing Dependency after Ischaemic Stroke Trial

Web: www.tardistrial.org Email: tardis@nottingham.ac.uk

Congratulations to... ***

- Barnstaple (North Devon), Bath (Royal United), Colchester, Dewsbury & District, Eastbourne General & Watford General Hospitals, for randomising their first TARDIS patients.

Welcome to...

- King's Mill, Gateshead (QE), Lewisham & Sheffield Hospitals - waiting to recruit their first patient.

Help, Tips, Clarifications

- Blood samples should be labelled with the full trial number C999/9999/ZZZ and say whether it is a DNA, plasma or serum samples and the Day taken i.e. 0, 7 or 35 (using a cryoware pen or special freezer label).
- There is a new 'withdrawal' CRF for completion (see attached) – please do this as soon as there is any indication that the necessary data cannot be completed. Please remember that it is very unusual for patients to completely withdraw from a trial.
- Avoid randomising probable cardioembolic strokes i.e. history of AF, paroxysmal AF, AF on ECG after onset.
- Please enter recruit trial number on the Consent Form/s before faxing to Nottingham and filing in medical notes and recruit's trial file. The MASTER consent form must be retained in the ISF or recruit's trial file.
- Day 35 form

The question 'How many tablets taken' refers to clopidogrel (where applicable). This does not include the loading dose, we just require entry of the number of tablets taken from the full box which was dispensed after randomisation.

Investigators

NEW Investigators

Before new investigators may work on TARDIS please ensure that the signature/delegation log is updated and the person is authorised by the PI with their delegated duties. The updated copy of the log needs faxing to the Co-ordinating Centre with their up-to-date signed and dated copy of their CV (preferably a short 1-2page CV as per the SRN layout which can be provided on request) and in-date GCP certificate. It is recommended GCP training is undertaken 2-yearly. We will then confirm if the paperwork is in order that the particular investigator may commence on the trial.

Investigators no longer working on the trial

Please update the signature/delegation log and fax this to us (0115 8230273) if any investigators leave the trial. This will allow us to remove them from our circulation list and de-activate their login details (where appropriate).



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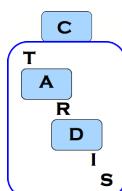
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Patient Details Form

This is a very important form that must be faxed to us at the same time as the consent form, within a week of randomisation. Please make sure that the GP details are correct at the time of completion and also that the telephone number of a further contact is collected, who does not live at the same address as the patient.

Resetting passwords

Please note the new contact if you require your password to be reset.

Yvonne.smallwood@nottingham.ac.uk Tel: 0115 8231770

Randomisation

We would like your help in randomising more patients within the first 24hrs of onset, rather than waiting the next day. Earlier treatment could benefit the patient.

Reduce queries to your site

Please fax the required documentation at your earliest to avoid unnecessary queries being raised to chase these documents.

Patient Details/Consent Forms/Proof loading doses given on day of randomisation

- within 1 week of randomisation

Radiology Scans i.e. CT/MR/Carotid Doppler reports (baseline and clinical)

- When reported

P-Selectin blood samples – new system

A new system for collecting the bloods for P-selectin testing is available. A few sites have already started using this. Full blood collection packs are being sent out to recruiting sites and will include all documentation and a powerpoint presentation for training purposes. We will be in touch with others shortly regarding sending supplies. If anyone has any queries / problems please do not hesitate to ring 0115 8230210. You can still continue to recruit before you receive these new kits. But once they have arrived, please take the blood samples for all participants.

(IMP) 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 acceptable temperature ranges, as the drug will need replacing if temperature is logged outside these limits.



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SUBMITTED BY:	DATE:	WITHDRAWAL FORM (SOURCE DATA)
RECRUIT'S TRIAL N°:		ISRCTN47823388
RECRUIT'S INITIALS:		CENTRE N°

TARDIS: Withdrawals

Please complete as soon as known and fax to 0115 8230273.

** For the safety of the patient, if they will not attend for face-to-face visits, which would include taking an FBC, then their antiplatelet medication may need to be reviewed **

Please try to not recruit participants who you believe will be likely to withdraw and ensure that participants understand their responsibilities in the trial.

It is rare that participants request to withdraw totally from a research trial.

If however a participant asks to withdraw from the trial, then please bear in mind that there are different levels/stages of withdrawals.

By asking questions as to why the participant wishes to withdraw, it may be possible to retain them in the trial, but please do not coerce participants.

For accurate completion of the trial, we need to be able to at least collect follow-up details at the day 90 telephone follow-up, made by the Co-ordinating Centre.

Withdrawn By:	Patient / Investigator	Date of withdrawal			
Participant will Continue Treatment	Yes / No /	N/A (past day 30)			
Day 7	<p>The participant will:</p> <p>Continue Day 7 face-face follow-up</p> <p>Allow Day 7 follow-up phone calls to home</p> <p>Allow Day 7 follow-up phone calls to GP as to vital status and recurrent events</p> <p>Not allow Day 7 follow-up in any way</p> <p>N/A</p>				
Day 35	<p>The participant will:</p> <p>Continue Day 35 face-face follow-up</p> <p>Allow Day 35 follow-up phone calls to home</p> <p>Allow Day 35 follow-up phone calls to GP as to vital status and recurrent events</p> <p>Not allow Day 35 follow-up in any way</p> <p>N/A</p>				
Day 90	<p>The participant will:</p> <p>Continue Day 90 telephone follow-up</p> <p>Allow Day 90 follow-up to GP as to vital status and recurrent events</p> <p>Not allow Day 90 follow-up in any way</p> <p>N/A</p>				

(please complete details on the next page)

SUBMITTED BY:	DATE:	WITHDRAWAL FORM (SOURCE DATA)
RECRUIT'S TRIAL N°:		ISRCTN47823388
RECRUIT'S INITIALS:		CENTRE N°

Further information/clarification:

SIGNATURE OF INVESTIGATOR	
DATE OF COMPLETION	

TARDIS TRIAL OFFICE:
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