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TARDIS NEWS

673

Recruitment at 31 Jan 2012

Aberdeen Royal Infirmary	12
Airdrie: Monklands	14
Ashford: William Harvey	1
Barnsley District Gen.	10
Barnstaple: North Devon D	2
Basildon University Hosp.	2
Basingstoke: Hampshire H	6
Blackpool Victoria	1
Bristol, BRI,	2
Chesterfield Royal	12
Colchester General	6
Countess of Chester	29
Croydon, London	9
Dewsbury & District Hosp.	6
Dorset County Hosp.	1
Eastbourne General	11
Forth Valley, Larbert	4
Gateshead, Q.Elizabeth	3
Glasgow Royal Infirmary	8
James Paget, Gt Yarm	1
Kettering General Hosp.	1
King's College, London	47
King's Mill, Sutton in Ash.	12
Leeds General Infirmary	27
Lincoln County	1
Leicester, LRI,	2
Margate, QEQM	15
NHS Fife, Kirkcady/Dunf	3
North Staffs, Stoke	53
Nottingham Univ Hosp.	68
Plymouth Hospitals	1
Princess Royal, H.Heath	3
Raigmore Hosp, Inverness	1
Rotherham Hospital	4
Royal Bournemouth	9
Royal Cornwall, Truro	17
Royal Derby Hosp	28
Royal Devon & Exeter	25
Royal Liverpool	7
Royal Preston	10
Royal Surrey, Guildford	10
Royal United Hosp,Bath	2
RVI, Newcastle	7
Sheffield Teach Hosps.	3
Southend University NHS.	3
Stockport, Stepping Hill	3
St Georges,London	60
The Calderdale Royal	23
The Ipswich Hospital	4
Torbay District Hospital	19
Univ.Hospital Aintree	28
Watford General	4
Wansbeck & N.Tyneside	4
Whitehaven/W.Cumb.Hosp	7
Whiston Hospital,Prescot	11
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 8230210*

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

Congratulations to….

William Harvey Hospital for randomising their first TARDIS patient.

Outstanding data

There are many outstanding entries to be made on the database, these include FBC results, both Day 7 and Day 35 data. Could we please ask all investigators to check their recruit data and enter any outstanding results as soon as possible as we are preparing for the next Data Monitoring Committee meeting. All entries need to be made at the latest by Friday 23rd March please, but sooner if possible.

Extension of 3-year Startup Period

We have received approvals from MHRA & MREC to extend the TARDIS startup period to the end of October 2012.

You will be receiving copies of these documents by email to forward to your local R&D Departments for their approval. The documents will also shortly be loaded onto our website – under Investigator Materials.

SICKNESS/MATERNITY LEAVE

Clarification has been received from the Sponsor regarding sickness or maternity leave of the Principal Investigator.

The signature/delegation log should always show a nominated deputy (or two) for the PI to cover absences such as sickness and holiday so that recruitment does not have to stop and that someone is available to assess SAEs for causality and relatedness to the IMP.

Longer planned absences such as maternity leave, or illness that is likely to become longer term would involve the deputy stepping up as official PI. For TARDIS this would require a substantial amendment to be submitted to MREC and MHRA for approval, together with your local R&D Office.

WEAKNESS CLARIFICATION

Please do not randomise patients with either lone hand or lone facial weakness. Also pins and needles or numbness without weakness in limbs does not meet the eligibility criteria for TARDIS.

British Heart Foundation
SRN Stroke Research Network
The University of Nottingham
UNITED KINGDOM · CHINA · MALAYSIA

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Help,Tips, Clarifications

Please do not delay randomisation by waiting for carotid scan results – randomise as early as possible. If the patient requires surgery then they will remain in the trial. The trial antiplatelets may be temporarily discontinued and then restarted if the participant is still within the 30 day treatment period.

Labelling P-selectin samples
Don't forget to enter the full trial id (C999/9999/ZZ), day (0 or 7) and the date the sample was taken on the samples prior to posting.

It is important at the Day 7 and 35 follow-up visits, that investigators take the Full Blood Count to ensure the continued safety of the participants.

If entering a 'bleed' outcome event, any clinical FBC results relating to the event should be submitted online. The question 'Was there a fall in Hb?' refers to any fall between the baseline FBC and the last FBC result entered. This relates to the question 'what was the event?' and either 'mild, moderate, severe' chosen depending on the drop in Hb.

Please continue to fax over the consent form/s and patient contact details within 3 days of randomisation. Faxed radiology reports (CT/CTA/MRI/MRA/Ultrasound), prove that loading doses of trial antiplatelets have been taken, and any additional Clinical Radiology forms can be sent shortly after. The fax cover page should be used. (http://www.tardistrial.org/TardisFormFaxCoverSheetV11.pdf)

Day 35 form – The question 'How many tablets taken' refers to clopidogrel (if taken). This only refers to the number of tablets taken from the blister pack (max 30) and does not include the loading dose which should have been given separately as soon as possible after randomisation.

SAE/Outcomes – if there is an extension of the randomising event, please enter this under an SAE. Only new Strokes/TIAs should be entered as Outcomes.

Transcranial Dopplers

At the last TARDIS Trial Steering Committee in December 2011, it was decided that the TCD part of TARDIS would no longer continue in 2012. We wish to express our thanks to all sites who have undertaken this part of the trial.

Recently uploaded forms

Outcome/SAE event form, v2.2 (pdf file)
Imaging form, v1.2 (pdf file)
MHRA approval letter, 18/10/2011 (pdf file)

Data Monitoring Committee report 28 November 2011 (pdf file)