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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 Tel: 0115 8230210

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Recruitment at 31 Aug 2011

Aberdeen Royal Infirmary	8
Barnsley District Gen.	8
Basildon University Hosp.	2
Basingstoke	6
Blackpool Victoria	1
BRI, Bristol	1
Chesterfield Royal	12
Colchester General	4
Countess of Chester	28
Croydon, London	8
Dewsbury & District H.	4
Dorset County H.	1
Eastbourne General	8
Forth Valley Royal,Stirling	1
Gateshead, QE	1
Glasgow RI	6
James Paget, Gt Yarm	1
Kettering General	1
King's College, London	28
King's Mill, Sutton in Ash.	7
Leeds General Infirmary	22
LRI, Leicester	1
Margate, QEQM	10
Monklands, Airdrie	13
NHS Fife	2
North Staffs, Stoke	45
North Devon District H.	2
Nottingham Univ Hosp.	52
Plymouth Hospitals	1
Princess Royal, H.Heath	1
Raigmore Hosp, Inverness	1
Royal Bournemouth	7
Royal Cornwall, Truro	17
Royal Derby Hosp	23
Royal Devon & Exeter	22
Royal Liverpool	7
Royal Preston	9
Royal Surrey, Guildford	8
Royal United H,Bath	2
RVI, Newcastle	3
Southend University NHS.	3
St Georges, London	49
Stepping Hill,Stockport	1
The Calderdale Royal	19
The Ipswich Hospital	4
Torbay District Hospital	18
Univ.Hospital Aintree	17
Watford General	1
Wansbeck & N.Tyneside	1
West Cumberland, Whitehaven	7
Whiston Hospital,Prescot	5
Yeovil District Hosp	9

Serious Adverse Events

by Associate Professor Nikola Sprigg
Independent SAE Adjudicator

Reporting of serious adverse events is an important aspect in all clinical trials for safety and governanace. TARDIS investigators have a responsibility to report SAEs in a timely and detailed manner. Furthermore, as the primary outcome in TARDIS is recurrent cerebrovascular events, it is critical that we collect high quality data on recurrent vascular events.
Whilst we appreciate that all investigators are busy and documentation needs to be kept to a minimum, we need to ensure that a necessary set of information is provided.
The following tips are aimed at improving the reporting process:

1) Is it an OUTCOME?
TARDIS is recording all vascular events AND all episodes of bleeding from enrolment to follow-up at 90 days. You will need to complete an outcome form for any of these events. The form will ask you for evidence to confirm the event – for example in bleeding events you will need to provide results of haematology blood tests. For cardiac events (MI, ACS) is it important that you provide ECG results and blood test (cardiac enzyme) results. These details should be entered on-line, eg ECG showed new ST elevation and Trop I was elevated at 199 (normal range less than 0.1). For recurrent stroke/TIA please ensure you give both clinical details and results of imaging: for example- sudden onset right arm and leg weakness, CT head shows new left parietal infarction. A copy of results (ECG, scan report, blood tests) should be faxed to the trial office but these results MUST be entered on-line.

2) Is it a SERIOUS adverse event?
Remember SAEs must be a *new* event that fulfils one or more of the following criteria: results in death, is life-threatening, requires inpatient hospitalisation or prolongs existing hospitalisation, results in persistent or significant disability/incapacity, results in a congenital anomaly/birth defect or is medically important.

For example; a urinary tract infection in an already hospitalised patient is not an SAE unless it is life threatening or prolongs the hospital stay by delaying discharge. Similarly, syncope or a fall is not an SAE unless it results in hospitalisation, prolongation of hospital stay, or causes significant disability.

3) What was the relationship to treatment and potential causality?
Investigators must consider whether the SAE happened before, during or after treatment. An SAE occurring during or shortly after treatment should not usually be classified as 'Definitely not' as it is impossible to exclude a possible relationship between the treatment and SAE.

4) Please provide enough information and clinical details on-line.
Death in itself is not an SAE; the cause of death is the SAE. Investigators need to provide enough information about the cause of death and evidence for it. For example, patient got pneumonia (provide details of clinical signs, chest x-ray results, blood tests) and then died. Information should be entered on the website rather than be faxed to the TARDIS office as the adjudication is done on-line.

TARDIS Trial Office

Division of Stroke
Clinical Sciences Building
Nottingham University
Hospitals NHS Trust
Hucknall Road - Nottingham
NG5 1PB

Chief Investigator
Prof Philip Bath
+44 115 823 1768

Trial Medic
Sandeep Ankolekar
+44 115 823 1769

Trial Manager
Sally Utton
+44 115 823 0287

Trial Coordinator
Margaret Adrian
+44 115 823 0210

Database Programmer
Liz Walker
+44 115 823 0285

Trial Statistician
Cheryl Hogg
+44 115 823 1670

Data & Imaging Officer
Tanya Jones
+44 115 823 1673

Follow-up Co-ordinator
Patrick Cox
+44 115 823 0288

Access/Passwords
Yvonne Smallwood
+44 115 823 1770

Serious Adverse Events (cont..)

Death unattended should only be used if the patient is found to have died and no cause is known. Investigators should seek information from other sources (GP, other hospital notes) if necessary.

5) Is the event expected?
A SUSAR only occurs when the event is UNEXPECTED. For example, if a recovered stroke patient suddenly dies due to pulmonary embolism resulting from an unrecognized deep vein thrombosis of a leg, this is an unexpected death for the relatives (and maybe for the doctors also), but it should not be coded as unexpected, as pulmonary embolism, is an expected adverse event in stroke patients. The majority of SAEs (pneumonia, cardiac events, falls) are expected events in stroke patients.

If you have any questions please do not hesitate to contact the TARDIS office for advice on 0115 8230210 prior to completion of the on-line form. Once the data is submitted it can only be updated by completing and faxing over a data correction form.

Investigator Meeting

Thanks to everyone who attended the UK Investigator Meeting at University Park, Nottingham on 6 and 7 September.

For TARDIS investigators there was an emphasis on SAE/Outcome completion, but the information is also applicable to all our trials. The more information entered (especially in the open text fields) when reporting an event, will cause less queries to be raised by the Adjudicator.
All sides from the meeting will shortly be available to view on the TARDIS website.

Congratulations to ..... ***

…. Bristol Royal Infirmary, Forth Valley Royal, NHS Fife, King's Mill, Wansbeck General, Royal Infirmary Leicester, Royal Victoria Infirmary Newcastle, QE Gateshead for randomising their first TARDIS patients.

Funding from 1/4/2012

Application for further funding has been made to the HTA in order to continue recruitment from 1/4/2012. We will contact all sites once we know the outcome, hopefully early in the New Year, if not sooner. Until that time we will continue to randomise under V1.2 of the Protocol.

Help, Tips, Clarifications

- It is important at the Day 7 and 35 follow-up visits, that you take the Full Blood Count in order to ensure the safety of the participants. Also if entering a bleeding outcome event, a clinical FBC relating to this event should also be submitted online.
- Please continue to fax over consent form/s and patient contact details within 3 days of randomisation. Faxed Radiology reports (CT/MR/Ultrasound), proof that loading doses have been taken and Additional Clinical Radiology forms can be sent shortly after. See our Fax Header on the website which should assist you - http://www.tardistrial.org/TardisFormFaxCoverSheetV11.pdf.

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SRN Stroke Research Network
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