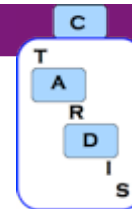


TARDIS NEWS

ISRCTN47823388
July 2014, Issue 14



1906

Recruitment at 8 July 14

International Denmark

Copenhagen University (NC)..... 15

Georgia

Tbilisi State Medical.....4

Tbilisi Central.....1

New Zealand

Palmerston North Hospital (NC).....5

UK *

Aberdeen Royal Infirmary.....39

Airdrie: Monklands.....26

Ashford: William Harvey.....23

Ashington: Wansbeck.....18

Barnsley District Gen.....28

Bath: Royal United Hosp.....9

Bournemouth.....18

Chertsey: St Peters.....9

Chester: Countess.....46

Chesterfield Royal.....22

Colchester General.....32

County Durham.....16

Derby: Royal Derby Hospital.....54

Dewsbury & District Hosp.....44

Doncaster&Bassetlaw.....9

Eastbourne General.....32

Exeter: Royal Devon.....50

Gateshead, Q.Elizabeth.....29

Glasgow Royal Infirmary.....16

Guildford, Royal Surrey.....13

Halifax, Calderdale.....37

High Wycombe.....17

Inverness, Raigmore.....26

Ipswich.....14

Kirkcaldy, Victoria Hosp.....14

Larbert: Forth Valley.....10

Leeds General Infirmary.....40

Leicester Royal Infirmary.....10

Liverpool: Royal.....47

Liverpool Aintree.....50

London: Barts.....8

London: Croydon.....10

London: Kings College.....118

London: St George's.....134

Macclesfield.....12

Mansfield, Kings Mill.....42

Margate, Queen Elizabeth QM.....38

Middlesbrough: James Cooke.....25

Newcastle, Royal Victoria.....18

Nottingham Univ Hosp.....156

Peterborough&Stamford.....5

Plymouth Hospitals.....10

Poole Hospital.....5

Prescot, Whiston.....23

Preston.....29

Rotherham.....14

Scarborough Gen.Hosp.....7

Sheffield Teach Hosps.....34

Southend:Southend Uni Hosp.....9

Stevenage:Lister Hosp.....9

Stockport, Stepping Hill.....8

Stockton on Tees.....15

Stoke on Trent, North Staff.....149

Sunderland City Hospital.....5

Torquay, Torbay.....43

Truro, Royal Cornwall.....18

Watford General.....6

Whitehaven, W Cumberland.....15

Winchester : Hampshire Hosp.....17

Wolverhampton:NewCross.....10

Yeovil District Hosp.....17

* Recruited at least 5 patients

Newsletter for the Triple Antiplatelets for Reducing Dependency after Ischaemic Stroke Trial

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

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

Recruitment Update

Thank you to all sites that have contributed to the excellent recruitment for June, where we recruited our most ever patients in one month – **94!!!**

8 sites recruited 4 patients or more and have had hampers sent to them as thanks. Well done to Nottingham, Preston, St George's, North Staffs, Dewsbury, County Durham, New Cross, UK and to Tbilisi State Medical Institute, Georgia.

Well done also to North Staffs for recruiting the fastest patient from stroke onset to randomisation in 3 hours 55 minutes.

As you know we have a target of 4,100 patients by end of April 2017. We need a recruitment rate of **65 patients per month** to achieve this.

Our average monthly rate over the last 6 months was 56, so we really need to keep up the recruitment.



Dr Shuja Puneekar and team at Royal Preston Hospital, UK

The Independent Data Monitoring Committee took place on 7 March 2014. The committee did not have any safety concerns and recommended that the trial should continue. The DMC letter is on the Documents Website.

TARDIS documents update...

Updates include

➤ New Protocol v1.5 (effective from 22/4/14)

➤ Updated GP letter v1.3

to be used at baseline
(further GP letters are sent out by the coordinating centre if patients are still on triple therapy beyond day 30 or on no medication after day 30)

➤ New Randomisation and updated Baseline CRF

- * Updated temperature IMP requirements.
- * Addition of MR diffusion imaging to widen inclusion criteria.
- * Update of dose ranges for international sites.
- * Helping to prevent and react to patients continuing on triple and dual (aspirin and clopidogrel) antiplatelet therapy beyond the maximum treatment period of 28-30 days.
- * Ensuring that after 28-30 days, patients go back onto guideline therapy, as per local practice.

- * Simplified baseline form to allow for quicker randomisation, split into two separate CRFs; we now have a randomisation CRF.
- * The key variables required for randomising a patient into the trial are on the randomisation form and further baseline information is now collected on the separate baseline form 24 hours later.

Protocol and GP letters have received all regulatory approvals-please ensure these documents are forwarded to R&D departments.



The University of
Nottingham

UNITED KINGDOM - CHINA - MALAYSIA

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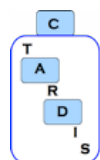
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Tips of the month

- Please advise us on **changes of PI's at local sites** in the following situations:
 - * Secondment for 6 months. This is a significant period of time so a formal change of PI needs to occur. Whilst the amendment goes through, the delegated deputy can take over with the PI supervising.
 - * Maternity or paternity leave for longer than 3 months.

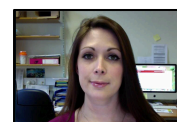
The deputy/co PI needs to be able and competent to take over the role of PI during periods of absence and signed on the delegation log, with CV, GCP certificate and an active password.

- When sending CT scans via CD, please ensure they are labelled in the following way: **TARDIS Centre number/Trial number/Initials.**
- Payments need to be made promptly for HTA rules so please forward all documents asap so we can action payments. Invoices are not required.

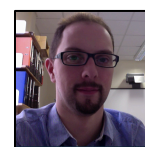
Welcome to...

Michael Stringer and Harriet Howard, who have recently joined the department as UK Trial Coordinators and will be working on the TARDIS trial.

Harriet Howard (UK payments, SAEs, Follow Ups)
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Tel: +44 115 823 1275



Michael Stringer (UK site monitoring, Follow Ups)
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★ Congratulations to ★

- London, Barts Health, UK; Birmingham Heartlands, Birmingham UK; Ayr University Hospital UK; Sunderland City Hospital, UK; Birmingham Good Hope Hospital, UK; Dudley, Russells Hall, UK; Coventry University Hospital, UK and London, Princess Royal, UK for recruiting their first patients!
- Tblisi State Medical Institute, Georgia for recruiting the first ever TARDIS patient in Georgia!
- Tblisi Central Hospital, Georgia for recruiting their first patient.
- Kings Mill Hospital for recruiting 6 patients within 30 days.

There will be a prize for the 2000th TARDIS patient recruited!

TARDIS recently attended

- SRN national meeting, Newcastle
- Trent, Thames and South West SRN annual meetings
- ISC, San Diego
- ESC, Nice
- NIMAST, N.Ireland
- Welsh Stroke Conference, June 2014

Future TARDIS events

- WSC, Istanbul, October 2014
- UKSF, Harrogate, December 2014
- ISC, Nashville, February 2015



Stand, ESC Nice, May 2014

Recently updated documents

- Randomisation choices forms v1.1
- GP letter v1.3
- Protocol v1.5



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