



TARDIS UK INVESTIGATOR TELECONFERENCE MINUTES

18 June 2010, 12:30pm

UoN attendees: Philip Bath, Sandeep Ankolekar, Margaret Adrian, Sally Utton

UK Attendees in Site number order:

Judith Clarke, Patrick Cox, Mina Patel	(C001, NUH)
Clare Buckley	(C003, Yeovil)
Rachel Jolly	(C004, West Cumberland)
Maggie Ball	(C007, Chesterfield)
Ben Hyams , Nikki Persad	(C008, Plymouth)
Leigh Barron, Angela Bowring	(C009, Exeter)
Nicola Rands	(C013, Ipswich)
Louise O'Shea	(C015, Dorset County)
Joanna O'Reilly,	(C020, St Georges)
Caroline lawlor	(C022, Guildford)
Liz Ronald / Ruth Graham	(C030, Glasgow RI)
Anna Orpen	(C037, Bournemouth)
Sharon Tysoe	(C039, Southend)
Deborah Dellafera	(C045, Basingstoke)
Jackie Coleman	(SESRN)

Welcome

Philip Bath welcomed everyone to the 2nd TARDIS teleconference.

Change to notes of last meeting March 2010 - Dr Muhiddin from Royal Derby Hospital was unable to attend and should be removed from the list of attendees.

Problems experienced with TARDIS website

Over the last couple of weeks there have been some problems reported whereby 'Database unavailable' messages occur and screens time out (Exeter, Bournemouth, Glasgow). This has been reported to the University IT staff and is being investigated. No cause has so far been found. A log will be kept so please report any problems to the TARDIS office.

[This fault appears to have been resolved – as nothing has been reported since the teleconference.]

Trial Bloods

'Optional' will be removed in next Protocol change in order to clarify that the trial bloods are part of the main trial. The only optional blood sample is the DNA sample and must not be taken if the recruit does not sign a separate consent form.

Demo website for investigators

In order to practice randomising patients, entering data, looking at entered data and generally finding your way around the TARDIS database, we have a 'Demo' database which is especially useful for new investigators, at:

<http://www.nottingham.ac.uk/~nszwww/tardis//tardistrialdb/demo/>

Investigator ID: demoinv1 – Password: Nottingham – PIN: 8888

Hospital Events form

The Hospital Event form needs completing for all recruits. Many are being completed and/or entered late. The Working Practice Document 006 (at <http://www.tardistrial.org/TardisWpd006HeFormV11.pdf>) explains in detail when and how to complete this form.

New updates of CRF/Working Practice Documents (WPDs)

The website is updated with new version of CRFs or Working Practice Documents as they are amended. It is suggested that investigators check our website regularly for the latest versions of these and don't print too many copies.

If we have your email address, investigators are also contacted by email to advise of any changes. Anyone who thinks they are not receiving these emails and wish to be added to the list, please contact the Trial Office on 0115 8230210.

Exclusion Criteria

We need to avoid wherever possible any patients with cardioembolic strokes. Patient who have had an MI up to 12 months prior to randomisation, have a history of, or new, AF (including paroxysmal AF), or patients with acute coronary syndrome should not be recruited.

Faxed forms required by Co-ordinating Centre

The importance was highlighted of faxing the consent form and patient details form, to Nottingham as soon after randomisation as possible. Preferably within the first 2 to 3 days.

SAE/Outcomes CRF

This form is being redesigned to make it easier to complete and should be issued shortly.

Update of Recruitment figures

To-date there are 144 recruits. 2/3rd stroke and 1/3rd TIAs.

Safety of Patients

The TARDIS Data Monitoring and Ethics Committee met in June to review the data and confirmed that the trial should continue. They will meet again in 6 months time.

Avoid Double-entry of same patient

If a problem occurs whilst attempting to randomise a patient and you are unsure if the patient has been randomised successfully – please do the following:

BEFORE entering all data again, log out, then back in again and check the screen showing all randomised patients and check to see if this recruit has been added – a line is given with date randomised, initials of recruit etc. Only try randomising again if it does not exist. The result of randomisation will remain available for 12hours.

Clarification of crescendo TIAs

For a patient to be eligible and included as a crescendo TIA, the index event is the last TIA that occurred and this event must fulfil the inclusion criteria.

Questions from Investigators

Scan Upload Facility

This facility is not yet ready and apologies were given for this. In the meantime investigators are being asked take a copy of the CT/MR to CD and store locally until the facility is available on the website.

Barriers to recruitment

a) Pharmacy:

Length of time to dispense medications can be up to a few hours. A possible solution may be to request pharmacy to dispense some stock to the ward.

As clopidogrel is an IMP, if stock is dispensed to a ward/clinic, then a temperature log needs to be kept as some wards temperatures get rather high in the summer months. Check with your local pharmacy regarding the actual temperature range required for storage, usually 25oC but may accept variable temps between 15-30oC – if the temperature goes out of this range then the medication needs destroying. Some sites can only log temp Mon-Friday 9-5pm due to lack of staff, but using a 'monitor' with records max and min temperatures will cover this.

b) Some sites can only recruit Mon-Friday, only a few recruit at weekends.

c) TIA patients are discharged early, therefore the cost of bringing the patient back for 2 visits and also persuading the patient to return twice has an affect on recruitment.

Availability of P-selectin tubes

Apologies given as these are not yet ready to send out due to stability issues.

Day 7 or Day 35 follow-ups

- a) Venues are variable at each hospital, clinics, outpatient clinics, TIA clinics can be used only if they correspond with the due dates for follow-up. Some sites are able to use hospital transport.
- b) Who can undertake these visits? Anyone on the log who has been given responsibility for this by the PI. Provided the investigator is trained in the procedures required i.e. phlebotomy, NIHSS, GCS etc, Home visits can be made if allowed by the recruiting hospital and depending on the distance. Individual hospital procedures must be followed.
- c) Costs: The cost of £30 insurance cover, at one centre, to cover home visits, using a Pool Car can be claimed for in the repayment of transport costs for follow-ups.
Taxis are costly. If a relative can bring the patient in then you can pay them mileage/car parking and claim reimbursement on production of signed receipts.

Frozen Samples

Please keep frozen samples on site until requested by the Nottingham Co-ordinating Centre

TIA – CT scan

If CT scan result comes back as 'normal' then the answer to the question 'is the scan is compatible with the new event' can be 'yes'.

MRI - Clinical Brain Scan

Yes we do require all printed reports of any radiology scans, together with encrypted unanonymised scans on CD or uploaded to the website, once the upload facility is ready to use.

Date of next teleconference: **Friday 1st October 2010 – 12:30 to 1:30pm**

(Note: please do not ring in after 1:30pm as we will be charged for your call even though the teleconference may have finished).