



TARDIS UK TELECONFERENCE WORKSHOP MINUTES

10 March 2010, 12:30pm

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

UK Attendees (11) in Site number order:

Pauline Fitzell & Helen Bearne, (C010, Torbay Hospital)
Khulood Muhiddin & Lorna Mills(C012, Royal Derby)
Mel Dickens (C016, Leicester)
Joanna Breeds (C018, Brighton)
Joanna O'Reilly (C020, St Georges)
Caroline Lawlor (C022, Guildford, Royal Surrey)
Maggie Bruce & Michelle Kemp (C031, Aberdeen)
Ruth Graham (Scottish Stroke Network)

. **Welcome**

Philip Bath welcomed everyone to the first TARDIS teleconference.

. **Questions from Caroline Lawlor:**

Q1) *Large amount of information to enter, it would be helpful to have a save option so can return to form later?*

We are aware of the 'problem' and it is not technically possible at present, but may be added in the future.

Q2) *If patient thrombolysed and has had a second scan at 24hrs, which scan do you use as the baseline scan?*

The scan taken immediately prior to randomization i.e. in this instance the 2nd scan.

Q3) *£30 is not enough for recruit's travel expenses and can be a hindrance to recruitment.*

Funding is cash limited to £30 per recruit. However different options can be used to reduce the cost :

- a) re-imburse recruit/relative for petrol used (at the current rate of your hospital for auditing purposes)
- a) use public transport and reimburse recruit/relative (where appropriate)
- b) use taxis but this option is quite expensive.

Also if 4 patients recruited, then the site is allowed to spend £120 overall for travel expenses. Some recruits will still be inpatients and therefore will cost nothing extra. Reimbursement will be on production of receipts as proof of expenditure by recruiting hospital site. Please ensure that the site number, recruit number and initials, together with which follow-up visit it refers to, is clearly marked.

Q4) Recruitment

Time spent doing sub-studies is not reflected in the recruitment rate i.e TARDIS with or without sub-studies counts as 1 patient for SRN/NIHR.

At present only sub-studies which need a separate protocol and consent form are eligible for additional recruitments. Complexity of the trial is not taken into account at present by SRN/NIHR.

For TARDIS the P-selectin measure is not optional; it is integral to the main trial. However the recruit may decline to have the DNA sample taken.

Q5) *Why are Scottish Sites unable to take part in Transcranial Doppler sub-study (RG-GRI)*
Most Scottish sites have Spenser machines which are not compatible with the TCD machine used in London and therefore these sites are unable to take part in this particular sub-study.

Q6) *Why does the printout giving the randomisation result have to be destroyed?*

To reduce bias of the investigators at Day 35.

The printout can be sent to Pharmacy with prescription if this is a requirement at any sites.

Other items Discussed:

A) Hospital Events Form

This must be completed for all recruits whether or not admitted to hospital as this is where the final diagnosis is entered.

B) Exclusion Criteria - clarification

Recruits who have had MIs (in last 12 mos) are excluded as the patient would require clopidogrel open label – cardioembolic causes i.e. AF may be warfarinised

C) Consent and Patient Details Form

It is very important to fax these two forms to Nottingham (0115 8230273) as soon as possible after randomization i.e. in same week. Monitoring of site starts here.

D) P-selectin query from Joanna Breeds, Brighton

A refrigerator is required to store the three activation tubes at present. A new system is being trialled whereby all tubes would be held at room temperature. Further information will be sent on this in due course. Ruth Graham at GRI advised they did not have any p-selectin packs. These will be posted to all recruiting sites when new system available.

E) Generic issue – pharmacy temperature log (PB)

The temperature of Clopidogrel (IMP) also needs logging on the ward if dispensed directly from the ward stock (only pharmacies at certain sites have authorised dispensing directly from ward stock). Max temp 25°C.

F) Frozen Samples – (GC Truro)

Frozen samples can be kept preferably at -70/80°C, however -20°C is acceptable at the moment, but they should be moved to a -70/80°C freezer whenever possible.

Take care labelling tubes, use cryoware pens, as labels tend to peel off.

G) Is a copy of the drug chart required.

Yes please, the page/s showing loading doses of trial antiplatelets.

H) Data queries

- a. When completing SAEs investigators should not take account of the treatment assignment
- b. Up to day 30 – on Outcome/SAE, if relationship entered as 'definitely/definitely not' to trial meds and the patient has been taking clopidogrel, the investigator will be asked to re-consider this decision.

I) Posted CDs containing CT scans (GC)

CDs can only be posted if encrypted at recruiting site, otherwise high fines can be imposed if this is not adhered to. The TARDIS Upload Facility is not yet available on the website, therefore sites to retain CDs until this is ready. The upload software needs un-anonymised data to confirm it is the correct patient and then the data is uploaded in an anonymised format.

If films have to be sent they must be couriered - both ENOS and TARDIS patients could be sent at the same time. Please ensure each is labelled with trial name and numbers.

Truro advised they are unable to encrypt CDs.

It was agreed that this was a useful forum and another teleconference would be arranged sometime in June 2010

Date of next teleconference: **Friday 18th June 2010 – 12:30 to 1:30pm**