PODCAST
Prevention of Decline in Cognition After Stroke Trial

PODCAST UK TELECONFERENCE WORKSHOP MINUTES

13 September 2012, 12.30pm

UoN attendees: Philip Bath (PB), Martha Mangoyana (MM), Sally Utton (SU), Kailash Krishnan (KK)

UK attendees (8): Anu Joyson (C25 Aberdeen), Madeline Duffy (C15 South Tyneside), David Broughton (C21 James Cook, South), Deborah Walstow (24, Doncaster & Bassetlaw), Natasha Dyer (C18 York), Donna Hayward (C5, Yeovil), Durairaj Ramesh (C4 Aintree), Maggie Ball (C10, Chesterfield)

1. Welcome and status
Philip Bath welcomed everyone to the call and outlined the general rules of engagement.

2. The minutes of the last meeting. SU
We are now working with the new protocol. Lipid targets have been reduced as many of the patients enrolled on the trial had target lipid levels. Therefore total cholesterol has been changed from <4.0mmol/L to <3.0mmol/L. This trial is aiming to drive a difference between the intensive and guideline groups.

3. Recruitment Update. MM
MM reported that we have 26 centres, 45 patients randomised, 112 patients screened and 51 failed screens. We have had a few screening fails owing to the patients screening appointment being arranged after week 26 which then does not leave much time for patients to get their bloods done and get a baseline appointment before month 7.

4. Intensive cholesterol lowering
PB reiterated the need to manage the intensive and guideline arms separately. Guidelines seem to be receiving intensive B/P management owing to their B/P readings reported. Intervention should not take place by trial staff for those patients randomised to guideline treatment. If there is a concern, please inform the GP to treat the guideline patients. If the guideline patients are treated differently to routine care, this could affect the trial objectives.

5. Intensive B/P lowering
We are not achieving the target of 125mmHg or below for the intensive B/P arm patients. PB is encouraging PIs to prescribe several antihypertensive medications rather than a maximum dose of one and prescribe one B/P agent at a time, with a gradual escalation dose, rather than an excessive escalation in a short space of time. Doses should be escalated/added every 2 weeks.

6. Lipid management

Most patients are on target prior to randomisation. The protocol change highlights the lowering of LDL cholesterol from 2 to 1.4 or below. Escalate Artovastatin or equivalent plus Ezetimibe within 3 months. Simvastatin is not recommended for the elderly (NICE guidelines), intensive lipid management. We need to demonstrate we can achieve these targets.

7. Sub study scans

PODCAST is investigating whether anything is happening in the brain during the trial, comparing the intensive patients vs. guideline patients. Therefore as part of a sub-study, we are urging centres to request CT/MRI scans for patients who have been in the trial for at least a year. The scans are not restricted to any appointments so they can be done anytime after a year. The sub study has been ethically approved and centres will be paid for the scans and the postage. We require volume data, rather than a cross section as the volume scans represents the whole of the brain.

8. Comments / Questions from Investigators

Natasha Dyer (York): What is the expected lipid levels for guideline patients as York are aiming for 3.5?

PB stated that it is difficult to conduct a trial whereby the guideline patients are being treated intensively as it is difficult to lower the lipids of the intensive arm patients in such a scenario. It is an issue if hospitals routinely practice intensive lowering of cholesterol and this may prevent centres participating in the trial.

Website time out: Investigators raised the website time out limit whilst conducting appointments. Some of the assessments are so long that there is fear that the PODCAST website will log off whilst patients are having their assessments and data would need to be re-entered.

Feedback from Lee Haywood (Programmer): The PODCAST website has a timeout limit of 3 hours that should give sufficient time for assessments and also allow time for a break during the visit, if required.

PB queried if there are any issues with the investigators regarding the escalation of trial dosages?

Natasha Dyer stated that patients have been taking control of their own dosing of medication. Patients are now starting to use the internet to find out more about the medications they are taking, therefore finding out more about side effects. This has resulted in some patients stopping or reducing the doses of their prescribed medication. PB stated that patients need to be encouraged to discuss their issues with the trial nurse/ investigators and not take matters into their own hands. Otherwise, this will become a compliance issue and impact on the trial.

Question from Dr David Broughton (South Tees Hospital): Would lowering B/P intensively make decline in cognition worse?

PB stated that evidence to show lowering B/P to prevent cognition decline is very weak. We need to conduct this trial in order to obtain evidence. Without the trial, we will not be able to answer the question.

Question from Natasha Dyer (York): What is the progress of the East Riding PCT approval?

MM will forward the PCT Approval to ND. Yorkshire CLRN has forwarded the favourable approval.

PB advised Investigators to use the e-CRF, as transcriptions can lead to discrepancies. If possible, investigators should enter data directly on to the PODCAST website and print the screen before submitting.

Question from SU: Has anyone used a "Floating appointments" since the new amendment? No centres have done any floating appointments to date. PB commented that patients should be invited to come back early to escalate doses appropriately. There is money for patients travel, so bring the patient back if needed.

UKSF: SU announced there will be a PODCAST Investigators Meeting at 17:15 hours on the 4th December 2012 at the UKSF (UK Stroke Forum) Harrogate.

9. Date of Next Telecon Workshop: TBC