PODCAST
Prevention of Decline in Cognition After Stroke Trial

PODCAST UK TELECONFERENCE WORKSHOP MINUTES

18 April 2012, 12.30pm

UoN attendees: Philip Bath (PB - Chief Investigator), Sally Utton (SU - Trial Manager), Lynn Stokes (LS - Trial Coordinator), Cyrille Correia (CC - Trial Statistician)
UK attendees (16): Leigh Wilkins (C01, Nottingham), Maggie Ball (C10, Chesterfield), Michelle Fawcett (C12, Newcastle), Deborah Dellafera (Basingstoke), Paula Sharratt (C08, Airedale), Judy Murdy (CTTL NESRN), Michelle Platton (C20 North Tees and Hartlepool), David Broughton (C21, Middlesbrough), Natasha Dyer (C18 York), Catherine Ovington (C03, Bournemouth), Val Hogg (C12 Newcastle), Lynn Johnston (C13 Bradford), Kirsty Harkness (Sheffield), Doireann Dickinson (C04, Aintree), Donna Hayward (C05, Yeovil), Christine Blacklock (C02, Whitehaven).

1. Welcome and status
PB welcomed everyone to the call.

2. The minutes of the last meeting were discussed and approved.
a. Cambridge Inventory. Kirsty Harkness (Sheffield) uses the Cambridge Inventory as a diagnostic assessment in her memory clinic). PB said that it was difficult to add formally at this stage but agreed it is a useful tool to obtain further information from the informant and would be a useful tool for the dementia adjudicators.
b. When does recruitment stop? The date mentioned in the protocol is 31/08/2012 but due to the slow start to recruitment we plan to continue recruiting to the end of the feasibility phase (31/08/2013). The Trial Steering Committee will decide if we are to go through to main phase funding. If we do not go through to main phase funding we will look at possible extra funding so every patient has a 6 month and 12 month clinic follow-up as well as a 12 month telephone follow-up. It is essential to show we can go forward.
c. PB emphasised the need for all patients to have full baseline lipids and BPs.

3. Recruitment. Update.
LS said there are now 23 centres, 27 patients randomised, 4 patients successfully screened and waiting.

4. Substantial Amendment
PB went through the proposed summary of changes, which are to be sent to Ethics shortly.
a. The intensive target LDL-C target will be changed from <2.0mmol/L to <1.4mmol/L and the intensive target for Total Cholesterol has been changed from <4.0mmol/L to <3.1mmol/L. The targets will be changed because half of the patients randomised so far were at target at

randomisation. We need to drive a difference between the intensive and guideline groups.
b. The telephone screening is to be conducted face-to-face at the local research clinic. This is to ensure the BPs collected are current and give a clear picture of what is happening with the patient's BP. NB if a patient has not had their lipids taken at the time of index event it is perfectly acceptable to obtain them at screening or ask them to go their GPs prior to this screening appointment as it is good practice for all stroke patients to have their lipids checked.
c. The HbA1c blood test is to be added to the bloods to be collected prior to the clinic appointments. It is a more accurate indicator of the patient's glucose levels as compared with fasting glucose.
d. Time between screening and Baseline has been reduced to 1 week.
e. Posterior strokes are now to be included. If you do find eligible patients in the next few weeks, who have had a posterior stroke, then please collect their details as they may still be in time to be included but do not take consent.
f. A 'floating' appointment, has been added to allow patients to be seen outside of the scheduled appointments. This will be very similar to the month 3 monitoring appointment and will allow clinical review of a patient in case of further escalation of drugs being required or possibly de-escalation of drugs, for example in the event of hypotension.
g. As we are not reaching the BP targets or the required differences between the intensive and guideline groups we will now see the patients every 6 months for clinic review. The new clinic appointments at 12 months, 18 months etc will only be clinical as the patient will still be contacted by the Co-ordinating Centre for blinded cognition questions at the 12 month, 18 month points etc.
NB. PB emphasised the need for a less timid approach to reaching the intensive targets. He also highlighted the point that PIs can add drugs at intervals if necessary eg 2 weeks after appointments. Any specific details/instructions can be recorded in the comments section.
h. Guideline dosages have been clarified in the protocol.
i. Some sections from the protocol have been removed and have been put into working practice documents. This makes the protocol much easier to read.
PB said that all the changes are to ensure we achieve the delivery of the trial. There will be an email to inform investigators when the changes are approved and can be implemented.

5. Comments / Questions from Investigators
Comment by PB, - advised centres not to get involved with the guideline patient's prescriptions.
This is because community practice won't be reflected if we intervene. It is important to advise the patient to visit their own GP if you have concerns regarding their BP, lipid levels and blood results etc. By intervening in the guideline patient's medications we are reducing the chance of PODCAST delivering.

Comment by PB - the scores from the patient visits should not be fed back to the centres as it is inappropriate in a trial context.

Question from PB to the live sites who have not recruited their first patient- What are the barriers to recruitment?
Christine Blacklock (02, Whitehaven) said they had experienced logistical problems as well as patients not meeting the inclusion criteria.
Maggie Ball (010, Chesterfield) said they have had a patient attending for Baseline but they failed consent. They have 2 patients waiting to be telephone screened and continue to screen for patients.
Leigh Wilkins (01, Nottingham) raised the issue of PI availability as having an affect on the number of patients being randomised.
Deborah Dellafera (Basingstoke) agreed that PI availability is an issue but PB clarified that despite some of the PODCAST appointments being lengthy the majority of the work can be done by the nurse and we have designed the forms to concentrate the work of the PI into specific sections. PB also highlighted the formal processes available to PIs to access funding and time for research work.

Question from Lynn Johnston, Bradford – Can we collect data for the appointments (clinic and monitoring) on paper forms if there is no computer access?
PB said this is not ideal but if it is unavoidable then print off the form from the live website as this will ensure all the data is collected.

Question from David Broughton, PI at Middlesbrough - should we advise patients to purchase home BP monitors?
PB agrees this is an interesting possibility but would rather not pursue this at the moment.

Question from Catherine Ovington, Bournemouth - when are the BPs taken?
Once the changes are approved the BPs will be collected at the new face-to-face screening appointment rather than taken from the hospital inpatient stay TPR chart (as is currently advised). This will ensure we have the most up-to-date picture of the patients' BPs.

Michelle Fawcett, Newcastle - when are the bloods taken? At index event, screening, or at GP?
The blood results used for the screening should continue to be the results obtained during the index event. If there are none taken during the index event then they can be requested as mentioned previously.

Paula Sharratt, Airedale - Can we telephone screen posterior strokes prior to the amendment being approved?
If they have already been screened on the live and they only fail on the posterior stroke criteria then please submit a data correction form (by fax) and amend once we have approval. For patients who have had a posterior stroke please collect their details as mentioned previously.

Date of Next Telecon Workshop: TBC