

**Prevention Of Decline in Cognition After Stroke Trial (PODCAST): A factorial randomised controlled trial of intensive versus guideline lowering of blood pressure and lipids**

**Progress July 2011**

**This is a generic report. If you require the number of recruits from each Trust or from each GP please get in touch with the research centre at your local Trust who will be able to provide this information. Similarly, if you require any details of local clinical and non-clinical adverse events that have that have occurred in the course of undertaking the research, again contact your local site.**

Chief Investigator: Professor Philip Bath  
Email: Philip.bath@nottingham.ac.uk

Trial Co-ordinator: Mrs Lynn Stokes  
Email: lynn.stokes@nottingham.ac.uk

Date when first patient was recruited: 07/10/2010 at Nottingham, Centre 01.

Proposed number of patients to be recruited to date: 119

Actual number of patients recruited to date: 10 as of 09/08/2011

Recruitment

Recruitment numbers are lower than expected because of delays in approval, which has impacted on site initiation visits being carried out, but more centres are now receiving approvals and site initiation visits are ongoing. Our objective is to get as many sites on board as soon as possible and support them to recruit to target. The objective for the next 12 months is still 1-2 patients per centre.

## Progress

We now have 14 live sites in the UK.

There have been 2 substantial amendments. The first substantial amendment addressed issues raised by the PCTs by clarifying that the treatment algorithms are only a guide; reconsent by patients when losing their capacity was stopped; GP involvement was clarified and updated; scan transfer and storage was updated.

The second substantial amendment has meant the following changes have been approved to help with the smooth running of the trial:

To simplify trial procedures, we will ask the same blood tests for all participants, irrespective of the trial arm, for the clinic follow-up visits.

An ECG will be taken or collected at each clinic visit. The ambulatory blood pressure monitoring, as part of the sub-study, will now be performed at all scheduled, follow-up clinic appointments. The updated protocol further clarifies that the GP does not need to be GCP trained as they will not be involved in screening and recruiting patients.

There are several hospital trusts who are in the final stages of their approvals process and will be having their site initiation visits in the coming weeks. PODCAST is part of a portfolio of trials from the Division so the team regularly attend conferences and meetings, both here and in the UK, to publicise our trials. We encourage new sites to join the study and actively support our existing sites to recruit.

## Media Coverage

There have been press releases from both funders: the Stroke Association and the Alzheimer's Society UK.

## Audit Reports

None available at present.