Birmingham Clinical Trials Unit
Parkinson's Disease Newsletter

PD MED News
November 2008

PD MED is a large, simple, 'real life' trial that aims to determine more reliably which class of drug provides the most effective control, with the fewest side-effects, for both early and later Parkinson's Disease.

Randomisation to both Early and Later disease arms will remain open until December 2009!

Randomisation to PD MED will remain open for one final year to allow the target recruitment for the later disease randomisation to be met and to enhance statistical power for the early disease randomisation. People with PD live for an average of 15 years with their disease, therefore, long-term follow-up of the PD MED randomised cohort will be required to assess reliably the relative clinical and cost-effectiveness of different classes of medication for Parkinson's disease: first results of the randomised comparisons are not expected before 2010 with a full HTA report in 2011. Continuing recruitment for an additional year will significantly enhance the sample size, will not delay publication - patients randomised in 2009 will have 2 years of follow-up by 2011 - and will enhance data on the newer preparations, thus increasing the clinical relevance of the study findings.
As highlighted by NICE, the questions addressed by PD MED remain the top research priorities in treatment of PD. Continuing recruitment will provide an opportunity for centres to continue contributing to the evidence base by randomising their patients rather than having to make non evidence-based treatment decisions. The recruitment extension should not be administratively burdensome for centres as the PD MED Study Office will submit the relevant paperwork details.

Save the date in your diary!
PD Collaborators' Meeting
18 - 19th May 2009

The meeting will again be held at the Jurys Inn and Botanical Gardens in Birmingham. The programme will include updates on PD SURG and the launch of PD REHAB (our new trial investigating the potential benefits of physiotherapy and occupational therapy for PD patients).

PD MED is funded by the NHS through its Health Technology Assessment Research Programme. It is supported by the Parkinson's Disease Society, the European Parkinson's Disease Association and the Parkinson's Disease Specialist Nurse Association

PD MED team: Cally Rick / Francis Dowling (0121) 415 9129 / 9127

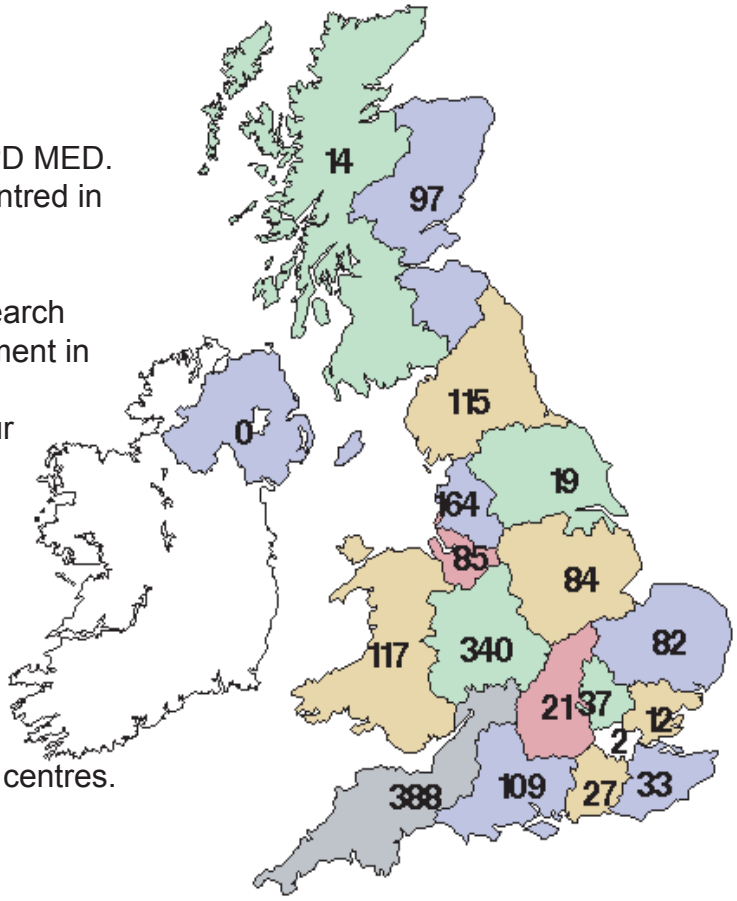
PD MED Recruitment

2008 has seen the best ever recruitment to PD MED. This recent surge in recruitment has been centred in regions of the UK supported by DeNDRoN.

We are hoping that the Comprehensive Research Network will have a similar impact on recruitment in other regions.
If you need any help getting in touch with your local research network, please let us know.

By the end of October, 1,791 patients had been randomised into PD MED: 1,374 into the early and 417 into the later disease randomisation of the trial including 30 re-randomisations.

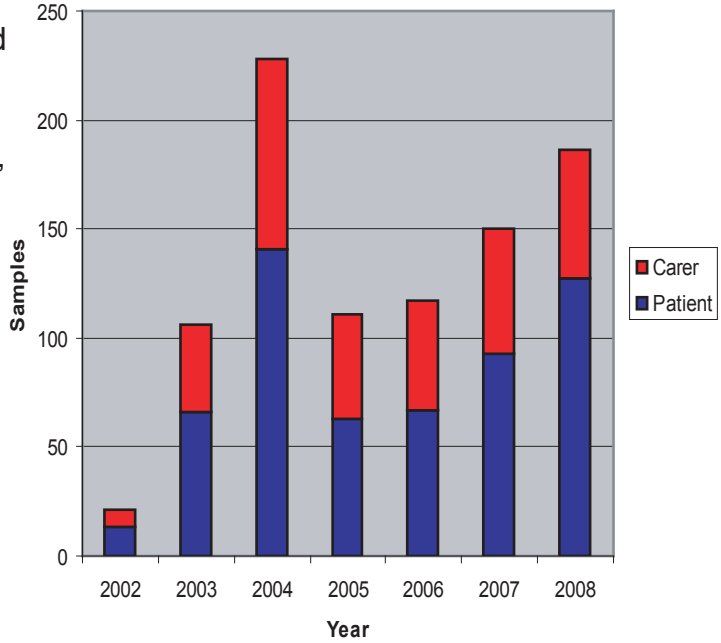
45 participants were recruited from overseas centres.



PD GEN - A DNA Bank

Birmingham University will be closed for Christmas. Please do not send PD GEN samples from 10th December to 2nd January.

We are starting to see an increase in recruitment to the other studies in the PD portfolio as DeNDRoN LRNs have come on line. Only a small proportion of PD MED and PD SURG patients have contributed samples to PD GEN. If you are in an area that is covered by a DeNDRoN LRN, they can provide support to enroll PD MED and PD SURG patients into PD GEN. We hope that this support will extend across the country once the CRNs get up and running.
Entering patients into PD GEN is a simple process, patients and carers (where possible) are consented for PD GEN and then asked to complete a quick questionnaire and provide a small blood sample. Recruitment in to PD GEN will continue until 2011, so there is plenty of time f or new centres (enrolled in the PD MED or PD SURG trials), to join PD GEN.
If you would like any information about PD GEN or who to contact at DeNDRON to find out what support is available in your area, please contact Francis Dowling on 0121 415 9127 or pd-trials@bham.ac.uk.



PD SURG NEWS

November 2008

The first draft of the PD SURG paper is currently being reviewed by the writing committee, It should be submitted before the end of the year.

A report of the PD SURG 1-year results is currently being prepared by the writing committee. It will be circulated to PD SURG Collaborators for comment prior to submission to the New England Journal of Medicine later this year.

We are continuing to collect data from the later time points in the trial and 2-year assessments should be available for all participants by the end of the year. The later follow up will provide a unique understanding of the longer term effects of DBS surgery. However, the form return rate has not been as good at later time points. There is still an opportunity, though, to improve the return rates significantly so please do keep sending us the annual forms. If an assessment is missed, it is particularly important for the statistical analyses to obtain data from the next assessment. If you are unable to see a patient in clinic at the annual follow up time point, can you please let us know so that we can send the questionnaires to the participants directly?

PDQ 39 (primary end point)

AssessmentDesc	PercNow	PercOverall
Baseline	97	97
1 Year	88	88
2 Year	83	75
3 Year	67	50
5 Year	63	20

Euroqol

AssessmentDesc	PercNow	PercOverall
Baseline	97	97
1 Year	88	88
3 Year	64	48
5 Year	63	20

UPDRS

AssessmentDesc	PercNow	PercOverall
Baseline	98	98
1 Year	85	85
3 Year	58	43
5 Year	50	16

Annual FU*

AssessmentDesc	PercNow	PercOverall
1 Year	89	89
3 Year	65	49
5 Year	60	19
6 Month Post-Op 1	86	77

Resource Usage

AssessmentDesc	PercNow	PercOverall
1 Year	84	84
2 Year	61	55
3 Year	67	49
5 Year	69	22

SF 36 (Carer QoL)

AssessmentDesc	PercNow	PercOverall
Baseline	96	96
1 Year	79	79
2 Year	82	76
3 Year	56	43
5 Year	62	20

*Some of these data can be obtained post hoc from medical records (Ann FU and 6 month post op forms).

There are enough participants who have not yet reached the later time points for the return rates to improve significantly. We will be performing longitudinal repeated measures analysis - so even if you miss one time point, please keep filling out the forms as the data will be used.

For more information please contact: Cally Rick c.e.rick@bham.ac.uk

PD REHAB News

November 2008

A Randomised Controlled Trial to Assess the Clinical- and Cost-Effectiveness of Physiotherapy and Occupational therapy in Parkinson's Disease.

The National Institute of Health Research has agreed funding for PD REHAB, a randomised controlled trial to assess the clinical- and cost-effectiveness of Physiotherapy and Occupational Therapy in Parkinson's disease. PD REHAB compares the immediate and prolonged (12 months post treatment) effects of domiciliary Occupational Therapy (OT) and Physiotherapy (PT) relative to no treatment.

Inclusion Criteria

- ✔ Idiopathic PD as defined by the UK PDS Brain Bank Criteria.
- ✔ Any PD patient who reports limitations in Activities of Daily Living
- ✔ The investigator is uncertain that the patient will require OT and/or PT during the 15 months of the trial.

Exclusion Criteria

- ✘ Dementia as usually defined clinically by the patient's physician.
- ✘ Received OT in the last two years or PT in the last one year.

The relative effectiveness of PT and OT will be measured by the participant's assessment of their quality of life, at baseline, 3, 9 &15 months. This will assess whether there has been a meaningful change in quality of life for the participant, immediately after therapy and, if so, if the effect is maintained 6 and 12 months later.

Resource usage, adverse events and carer quality of life will also be measured, to allow the calculation of not only the effectiveness but the cost effectivensss of therapy.

PD REHAB Projected Timetable

Time	*Action*
September 2008	NRES application for trial submitted
December 2008	NRES approval obtained and protocol published
January 2009	Trial officially commences with HTA Trial Manager and Data Manager appointed
February 2009 onwards	Applications for SSA and R & D approval submitted
May 2009	Trial launch meeting with collaborators (#1)
July 2009	Recruitment commences in ‘start up’ centres
January 2010	All 40+ centres recruited
May 2010	Collaborators’ meeting (#2)
July 2010	All centres recruiting
May 2011	Collaborators’ meeting (#3)
July 2012	Recruitment completed
October 2012	Last patient completes treatment
October 2013	Last patient completes 15 month follow up Data analysis commences
December 2013	Results available HTA report written Paper submitted for publication Final collaborators’ meeting (#4)

The Trial Launch Meeting will be held on the 18th May at the Botanical Gardens In Birmingham

If you would like any further information about this trial, please contact:
Carl Clarke - c.e.clarke@bham.ac.uk, Cath Sackley - c.m.sackley@bham.ac.uk
Cally Rick - c.e.rick@bham.ac.uk