

## PD MED

A large randomised assessment of the relative clinical and cost-effectiveness of classes of drugs for Parkinson's disease.

[Recruitment \(/research/activity/mds/trials/bctu/trials/pd/pdmed/investigators/recruitment.aspx\)](#) has closed to the PD MED study and results are being prepared for publication.

### Design

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PD MED is a large, simple, "real-life" trial that aims to determine much more reliably which class of drug provides the most effective control, with the fewest side-effects, for both early and later PD. Patients with early PD are randomised between DA (Dopamine Agonist), MAOBI (monoamine oxidase type B inhibitors) and LD (Levodopa) alone, with the option to omit either the MAOBI or LD alone arm. Those whose disease is no longer controlled by their first class of drug, after dose titration and/or addition of LD, are randomised between COMTI (catechol-O-methyltransferase inhibitors), MAOBI and DA, with the option to omit either the MAOBI or the DA arm. The main outcome measure is the patient-rated PDQ-39 quality of life scale, which assesses all aspects of the patient's life, and is sensitive to changes considered important to patients but not identified by clinical rating scales.

In order to recruit the large number of patients needed to provide reliable answers, and to maximise the clinical relevance of the findings, the trial is designed to fit in with routine practice as far as possible and to impose minimal additional workload: clinicians can use the specific drug within each class that they prefer, treatments are prescribed in the usual way, and extra clinic-based tests and evaluations have been kept to a minimum (the majority of assessments are by postal questionnaires to patients and carers).

### Aim of Study

PD MED is a large randomised clinical trial to evaluate the clinical and cost-effectiveness of different classes of drugs in patients with Parkinson's

### Setting

In over 80 neurology & care of the elderly units throughout the UK.

### Target population

Patients with Parkinson's of any age.

### Measurement of outcomes and costs

The primary outcomes will be the patient's self-evaluation of their functional status and quality of life (using the PDQ-39 questionnaire) and cost-effectiveness (EuroQoL EQ-5D).

Secondary endpoints will evaluate other aspects of functionality, and safety:

- Cognitive function (MMSE)
- Well being of carers (SF-36)
- Resource usage
- Toxicity and side-effects, including mortality rates
- Time to onset of motor complications (early disease randomisation only) and time to surgical intervention or start of apomorphine (later disease randomisation only)

These assessments will be completed before randomisation and by post at 6 months and then annually thereafter.