One to watch

This report reviews the PD Med Study, the results of which are due to be published soon.

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Parkinson's disease (PD) is one of the commonest causes of disability in older people with at least 8,000 new cases diagnosed each year in the UK alone. Levodopa (LD) controls symptoms for most patients but long-term use is associated with motor complications. A number of other drugs have been used, either alone or with reduced doses of LD, in an attempt to delay the onset of motor complications, or to control complications in later disease once they have developed. These agents have primarily been from three classes of drug: dopamine agonists (DA), monoamine oxidase type B inhibitors (MAOBI), catechol-O-methyltransferase inhibitors (COMTI).

All of these drugs are beneficial when used alone, but there remains uncertainty about their relative effectiveness. One reason for this is that previous comparative studies included too few patients, and most had inadequately short follow-up. A second problem is that the main outcome measures used in previous studies have been clinician-rated assessments of motor impairments and disability, which fail to assess the impact of the disease on the whole patient. For example, a recent agonist trial demonstrated a delay in time to onset of motor complications with DA, but at the expense of poorer control of the symptoms of PD, and an increase in hallucinations. Depression, dementia and sleep disturbance are other common problems that may be more important for patients and carers than motor complications. Another uncertainty is the role of the MAOBI, selegeline, which may be neuroprotective but was reported to increase mortality in one trial—although this has not been confirmed in other studies. DAs and COMTIs are considerably more expensive than either LD or selegiline and better evidence is needed on the balance of benefits and risks of these drugs to establish their cost-effectiveness.

What is the trial?

PD MED is a large, simple, "real-life" trial that aims to determine much more reliably which class of drugs provides the most effective control, with the fewest side-effects, for both early and later PD. Patients with early PD are randomised between DA, MAOBI and LD alone, with the option to omit either the MAOBI or LD alone arm. Those with later PD are randomised between COMTI, DA and MAOBI, with the option to omit either the DA or the MAOBI arm. The main outcome measure is patient-rated quality of life, using the PDQ-39 scale, which assesses all aspects of the patient's life, and is sensitive to changes considered important to patients but not identified by clinical ratings.

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 was 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).

Recruitment

The trial has recruited 2120 patients. Of these 2120 patients 1620 are in the early disease arm and 500 are in the later disease arm.

References

1. http://www.pdmed.bham.ac.uk/investigators/