A large randomised assessment of the relative cost-effectiveness of different classes of drugs for Parkinson's disease (PD MED)

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Title of project or programme

Title of PI A large randomised assessment of the relative cost-effectiveness of different classes of drugs for Parkinson's disease (PD MED)

Principal Investigators of project/programme grant

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Source of funding information

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1876454

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144

The project/programme is most relevant to

Parkinson's disease

Keywords

Parkinson Disease

Research abstract in English

Clinical trials comparing different classes of Parkinson's disease drugs have been too small for reliable conclusions, have used inappropriate surrogate endpoints, and follow-up has been too short to evaluate long-term benefits and toxicity.

This large (5000 patient), pragmatic, 'real-life' randomised trial addresses four fundamental, unanswered questions about PD treatment: what are the costs and benefits of: LD-sparing therapy (DA or MAOB inhibitors) compared to LD alone in initial treatment; DAs compared to MAOB inhibitors as initial LD-sparing therapy; DAs compared to DDIs (COMT or MAOB inhibitors) when motor fluctuations develop on LD alone; COMT inhibitors compared to MAOB inhibitors as DDI in advanced disease. Two separate 3-way randomisations allow classes of treatments for early and advanced disease to be investigated. Secondary objectives are to identify factors that might predict response to particular classes of drug and to provide a large collaborative framework within which other studies – in particular of neurosurgery and genetics – can be undertaken.

Lay summary

Parkinson's disease is a movement disorder that causes stiffness in the muscles, slowness, and tremor. These symptoms appear over many years and are caused by a reduction in the numbers of brain cells that produce a chemical called dopamine.

Several different types of drugs (mainly levodopa, dopamine agonists, MAOB inhibitors and COMT inhibitors) are used to control the symptoms of PD, with some doctors preferring one type and other doctors another.

However, little is known about how the drugs compare with each other and whether or not some provide better overall quality of life for people with PD. The only reliable way to find out which treatment achieves the best control of symptoms with the fewest side-effects is through what is called a clinical trial weighing up all of the advantages and disadvantages of each type of drug and seeing which is best overall.

PD MED is a large national clinical trial comparing the different drugs for PD. Patients who agree to take part are allocated, at random, to be treated with one or other of the different types of drug. These are prescribed by their doctor in the usual way and the patient is asked to complete questionnaires every year, for at least 5 years, to say how the drugs are affecting them. The patient's carer, if they have one, is also asked how helping to look after someone with PD affects their life. The questionnaires are sent out by post and no extra clinic visits are necessary.

The study started in November 2000 and first results are expected in 2006. PD MED is organised by the University of Birmingham Clinical Trials Unit, and funded by the NHS Health Technology Assessment programme. No companies are involved.

Further information is available from the PD MED study office, BCTU, 1 Somerset Rd, Birmingham B15 2RR, tel: 0121 687 2315, or by e-mail from pd-trials@bctu.bham.ac.uk or from the PD MED website www.bctu.bham.ac.uk

In which category does this research fall?

• Clinical research