



# Information for patients and their families/ carers

PD MED is a large national research study of treatments for Parkinson's disease (PD for short).

## **What is Parkinson's disease?**

PD is a movement disorder that affects various parts of the body, causing stiffness in the muscles, slowness, difficulty when starting movements, and tremor in some people. This is caused by a reduction in the numbers of brain cells that produce a chemical called dopamine. These symptoms appear over many years but drug treatments can help slow the effects of this process.

## **What drugs are currently available?**

Several different types of drugs are available to treat the symptoms of early PD. These drugs fall into a number of different categories (such as levodopa, dopamine agonists and MAOB inhibitors), and within each class there may be more than one drug available. We know from previous studies that each of these types of drug can be effective at controlling symptoms of PD and all of these treatments have been widely used, with some doctors preferring one type and other doctors another.

If your PD has progressed (advanced PD) and the drugs you have been taking are now no longer able to control the symptoms effectively you can still enter the trial. It is possible that changing the drugs you receive will help.

## **If these treatments are available why do we need a clinical trial?**

Although we know that these drugs do work, little is known about how these drugs compare with each other and whether or not some are better than others. Furthermore, the impact of the drugs on the daily life of people with PD (and on their carers) has not been investigated thoroughly. PD is, unfortunately, a common condition and we need to be absolutely sure that any new – and possibly expensive – drugs really are better than the older drugs before they become standard treatment. This means weighing up all the advantages and disadvantages of each type of drug and seeing which is best overall. This is what we hope to find out from the PD MED study.

## **How do I know if I can take part?**

Patients can enter the early arm of the study if they have recently been diagnosed with PD and have not been taking levodopa for more than 3 months, or can enter the advanced arm of the study if their current therapy is not working well enough. The study is aiming to recruit over 2500 patients in total.

## **Which patients will get which class of drug?**

### **For early disease:**

Since we do not know which class of drugs is best, we need to compare them to find out. In order to do this, patients will be allocated to one of three groups at random by a computer at the central study office. If your doctor thinks that all three drugs would be suitable for you, you will have an equal chance of drawing either:

- levodopa alone,
- dopamine agonist (this increases the amount of dopamine available in the brain), or

- MAOB inhibitor (this stands for monoamine oxidase type B inhibitor and works by reducing the breakdown of dopamine in the brain).

If your doctor feels that it would be inappropriate for you to receive one of the drugs (either levodopa or MAOB inhibitor), you will just be allocated between the other two, and you will have a 50:50 chance of receiving either of them. [If your doctor believes that neither levodopa alone nor a MAOB inhibitor are suitable for you, you will not be eligible for the study.]

### **For advanced disease:**

Since we do not know which class of drugs is best, we need to compare them to find out. In order to do this, most patients will be allocated to one of three groups at random by a computer at the central study office and you will have an equal chance of drawing either:

- dopamine agonist (this increases the amount of dopamine available in the brain),
- MAOB inhibitor (this stands for monoamine oxidase type B inhibitor and works by reducing the breakdown of dopamine in the brain), or
- COMT inhibitor (this stands for catechol-O-methyltransferase inhibitor and works by reducing the breakdown of levodopa in the brain).

However, if you have previously taken a dopamine agonist or a MAOB inhibitor (or if your doctor considers that a MAOB inhibitor would not be appropriate for you), you will only be allocated between the other two groups, and you will have a 50:50 chance of receiving either of them. [If your doctor feels that neither a dopamine agonist nor a MAOB inhibitor are suitable for you, you will not be eligible for the study.]

If more than one drug is available within the class to which you are allocated, your doctor will be able to choose which one to give you. Your doctor may also continue to give you levodopa if this is felt to be necessary. Whatever drug, or drugs, you receive during the study, you will still have access to the same medical and nursing support that would be provided if you were not in the study.

### **What does the PD MED Study involve?**

Entry into the study does not require any extra physical tests at all and no extra clinic visits are necessary as part of the study. Patients will visit their hospital doctor as usual. Each patient will be asked to complete a straightforward set of questions when they enter the study, 6 months later, 12 months later and then annually for another 4 years. Your carer, if you have one, will also be asked to answer some questions so that we can find out how helping to look after someone with PD affects their life. These questionnaires will be sent to you, and your carer, by post and a postage-paid envelope will be provided for their return. It should not take more than half an hour to complete them each time.

The study involves taking the drug, or drugs, allocated regularly as prescribed by your doctor. The actual regimen will depend on which drugs you receive and how severe your symptoms are. Your doctor will explain how and when the drugs should be taken. It is important that you tell your doctor of any changes in your symptoms so that the dosage of the drugs can be adjusted if necessary.

### **What are the risks of taking these drugs?**

Doctors generally agree that all the drugs prescribed in this study are safe but, as with any treatment, we can not guarantee that there will be no side effects. Your doctors will tell you about the possible side effects of the treatments that you might receive. It is important that you tell your doctors if the study drugs cause upsets so that they can decide whether other

treatment is required or the drug needs to be stopped. If new information comes to light during the course of the study, your doctors will tell you about it and discuss with you whether you should continue in PD MED.

### **Are there any benefits for me from taking part in the study?**

All of the treatments being used in this study are known to help control the symptoms of PD and are already widely used, so the treatment you receive will be at least as good as that available outside the study. We hope that the information obtained from this study will help us to treat patients with PD more effectively in the future.

### **What will happen to the results of the study?**

At the end of the minimum follow-up period for the trial, the answers you provide in the questionnaires will be analysed and a report written for a leading medical journal. The NHS will help ensure that UK doctors are aware of the results, so that patients can be treated with proven, effective treatments.

### **Who is organising and funding the study?**

The central study organiser is the University of Birmingham Clinical Trials Unit, which has experience of running very large trials like PD MED. The study is funded by the NHS Research & Development Programme. The doctors involved are not being paid for recruiting patients into the study. The study has also been reviewed by the West Midlands Multi-centre Research Ethics Committee and the Local Research Ethics Committee at your hospital.

### **Will participation in the study affect my legal rights?**

There are no special arrangements for compensation in the (unlikely) event that you are harmed as a result of taking part in the study. But, whether or not you take part, you will retain the same legal rights as any other patient treated in the NHS.

All information collected in the study will remain strictly confidential in the same way as your other medical records. Your GP will need to be told that you are taking part in the study as he/she usually supplies your prescriptions. The information will be put into a computer and analysed, but you will not be identified when the results are reported.

### **Do I have to take part in the study?**

No, you do not have to take part in the study, or give a reason if you choose not to. It is up to you to decide. If you do decide to take part, we will ask you, and your carer if you have one, to sign a consent form indicating that you understand what the study involves. You will be given a copy of an information sheet and the signed consent form to keep. Your hospital doctor will then call the study organisers to enter you into PD MED.

### **Can I withdraw from the study?**

Yes, you can decide to withdraw from the study at any time. Signing the consent form does not commit you to receiving the treatment allocated and withdrawal will not affect the standard of care that you receive subsequently. If you do change your mind later you do not have to give a reason, but it would help our research if you could still complete the questionnaires to let us know how you are doing.

### **Do you have any other questions?**

If you have questions about the study, feel free to ask your hospital doctor or nurse.