



PD MED TRIAL SCHEMA

ELIGIBILITY

- Early disease** randomisation: Patients with newly or recently diagnosed PD (Note A) requiring medical therapy. No prior, or less than 6 months, treatment with PD medication.
- Later disease** randomisation: Patients with PD who develop motor complications that are uncontrolled by their current therapy: either levodopa (LD) alone or LD with the addition of a dopamine agonist (DA) or a monoamine oxidase type B inhibitor (MAOBI).
- Both randomisations: Patient not demented, able to give informed consent and able to complete questionnaires.

Note A: See Appendix A for diagnostic criteria for PD

RANDOMISATION

- Randomisation is based on the "uncertainty principle". That is, if there is a definite indication for, or a definite contraindication against, a particular class of drug, then the patient is not eligible for a randomisation that includes this class of drug (Note B). If, however, the doctor is substantially uncertain which class of drug a patient should be offered, that patient is eligible to be randomised. Options are (Note C):

Note B: If one class of drug is contra-indicated the patient can still be randomised two-ways between the other two classes in both early and later disease (see protocol sections 2.2 and 2.3)



Note C: A patient who was initially entered into the early disease randomisation may also be entered into the later disease randomisation if motor complications subsequently develop

TELEPHONE RANDOMISATION

- Obtain patient's consent (Appendix C).
- Administer baseline assessments (section 5.3)
- Prepare for telephone questions using the randomisation notepad (see Note D).
- Telephone or fax the randomisation service (contact details below).
- When all the relevant questions on the randomisation notepad have been answered, a treatment allocation and patient reference number will be given.

Note D: The person randomising will need to answer all questions on the randomisation notepad (Appendix H).

TREATMENT

- The patient should be prescribed the class of drug to which they were allocated at randomisation.
- The specific drug used within this class, and drug dose and schedule, is up to each clinician's preference and local practice (Note E).
- All other management is as considered appropriate by the responsible physicians.

Note E: Guidelines are provided in Appendix N and clinicians are referred to the Summary of Product Characteristics for further information.

FOLLOW-UP

- The majority of assessments will be patient (or carer) based, with postal questionnaires at 6 months and 1 year after entry, then annually (see section 6.4)
- Once a year, clinicians will be asked to fill in a simple form giving details of any changes in disease status or therapies used.

FOR RANDOMISATION, TELEPHONE (FREEPHONE IN UK): 0800 953 0274
OR +44 (0)121 415 9129 FROM OUTSIDE THE UK OR FAX 0121 415 9135

For queries and trial supplies, contact the PD MED Trial Office, University of Birmingham Clinical Trials Unit, Robert Aitken Institute, Division of Medical Sciences, Vincent Drive, Edgbaston, Birmingham B15 2TT
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