THE CONDUCT AND MANAGEMENT OF LARGE CLINICAL TRIALS IN HYPERTENSION

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CONTENTS

ABSTRACT

Large multicentre studies are difficult to conduct and are expensive in both human and financial resources, yet they are essential in common conditions such as hypertension and hyperlipidaemia if important questions of morbidity and mortality of the condition and its treatment are to be answered. They must also be able to gather large amounts of data before the therapy being studied becomes outdated.

The first Study in this thesis describes and evaluates an economical method of collecting a large amount of data on thousands of patients suffering from essential hypertension. It establishes the reliability of the data collected in this way. The tolerability of antihypertensive drugs was assessed by comparison of the prevalence of adverse medical events reported by treated hypertensive patients and those who were untreated. This confirmed the impression that patients suffering from a symptomless condition, essential hypertension, did not tolerate the medications studied well.

The study also provided the largest single volume of information on the tolerability and effectiveness of nifedipine, at the time, the second most commonly prescribed antihypertensive drug. These data caused the world wide prescribing information for nifedipine to be changed.

The relationship between body mass index and diastolic blood pressure was explored in this large population and only a weak positive correlation between the two was found.

The generally poor tolerability of antihypertensive drugs led to the consideration of whether doctors neglected the non-pharmacological treatments for hypertension. The Study described in Chapter 4, shows that the provision of this advice could be better and more consistent.

Studies conducted as part of the development of new medicines are now required to be conducted to the standards of "Good Clinical Practice" as described by the Food and Drug Administration of the United States. A computerised system for patient tracking and the successful management of such clinical trials is described and evaluated in Chapter 3.