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The Anglo-Scandinavian Cardiac Outcomes Trial (ASCOT): baseline demography of randomised subjects and BP changes after 18 months.

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Background

ASCOT is a prospective, randomised, open blinded endpoint trial designed to test the primary hypothesis that an antihypertensive regimen comprising a calcium channel blocker (amlodipine) ± an angiotensin-converting enzyme inhibitor (perindopril) is more effective than a β-blocker (atenolol) ± a diuretic (bendroflumethiazide-K) in the prevention of coronary heart disease (CHD) in hypertensive subjects aged 40-79 years. Incorporated into a 2X2 factorial design is the test of a second hypothesis that the addition of lipid lowering with a statin (atorvastatin) compared with placebo will further protect against CHD endpoints in those hypertensive subjects with a total cholesterol ≤6.5 mmol/l.

Methods

ASCOT will randomise over 19,000 hypertensive patients with three or more additional Cardiovascular risk factors to the different treatment regimens by 26 May 2000 with an average follow-up period of 5 years.

Results

By May 2000 over 19 300 patients, mean age 62.6 ± 8.5 years (22% previously untreated) had been randomised, of whom 48% and 52% respectively had 3 and ≥4 risk factors. The prevalence of these risk factors among those randomised were:

Table 1

<i>Risk factor</i>	<i>%</i>	<i>Risk factor</i>	<i>%</i>
≥ 55 years	83	Total: HDL-cholesterol ratio ≥ 6	24
Male	74	LVH	14
Microalbuminuria/ Proteinuria	64	Abnormal ECG	15
Smoker	32	Prior vascular events	17
Family history of CHD	30	NIDDM	22

Fifty-one percent of patients have been randomised into the lipid-lowering limb of the study. Mean BP levels at baseline of the first 13,718 patients randomised, and at five follow-up visits, are shown in Table 2.

Table 2

	Baseline	<i>Follow-up (months)</i>				
		1.5	3	6	12	18
No.	13718	10524	9121	6799	3074	598
SBP mm Hg	163.8	154.0	149.5	146.7	144.4	141.9
DBP mm Hg	94.4	87.9	85.8	85.3	84.2	82.5

Conclusion

After 18 months using ASCOT's structured treatment algorithm good BP control has been achieved among the majority of patients randomised. ASCOT is the only trial to compare the efficacy (in terms of CHD prevention) of two combinations of antihypertensive drugs and will have over 80% power to detect a 20% difference between the two antihypertensive regimens.