A DOUBLE-BLIND TRIAL IN HYPERTENSION COMPARING BAYCARON (FBA 1500), HYDROCHLOROTHIAZIDE AND PLACEBO*

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SUMMARY

A double-blind study carried out on volunteer patients with medium to severe grade II hypertension, did not show any statistically significant difference between treatment with Baycaron 25 mg daily and hydrochlorothiazide 50 mg daily.

A double-blind trial was undertaken in Port Elizabeth on 60 volunteer White patients and 60 volunteer Bantu patients suffering from medium to severe grade II hypertension, comparing the effects of Baycaron (FBA 1500) 25 mg tablets, hydrochlorothiazide (HCT) 50 mg tablets and placebo tablets daily.

MATERIAL AND METHOD

The tablets were prepared to look identical, A—Baycaron, B—hydrochlorothiazide and C—placebo, and were packed in samples numbered from 1 to 120 on the basis of random distribution. In both groups of patients 20 patients each were treated with preparation A, B and C respectively and administered the same dosage, i.e. 2 tablets daily. The White patients were treated for 12 weeks and the Bantu patients were treated for 2 weeks. Neither the doctor nor the patient knew which preparation was being used in each particular case until the trial was completed. Before starting the trial and after 2, 6 and 12 weeks in the White patients and at the beginning and after 2 weeks in the Bantu patients the following tests were carried out: the measurement of blood pressure, weight, and serum sodium, serum potassium, and serum urea concentrations. Forty-nine protocols from the White patients and 57 of the Bantu patients could be evaluated.

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RESULTS

The results of tests carried out on White patients before and at the end of 12 weeks' treatment and in Bantu patients before and at the end of 2 weeks' treatment are given in Table I.

CONCLUSION

The double-blind trial with Baycaron, hydrochlorothiazide and a placebo was laid out and conducted on exact biochemical criteria with 120 hypertensives (60 White patients, 60 Bantu patients).

The evaluation of 106 protocols which could be referred to and in which the tests were completed (blood pressure, weight, potassium, sodium, urea) did not reveal any statistically significant difference between the Baycaron-treated group and the hydrochlorothiazide-treated group. The average fall of blood pressure was 21/12 with Baycaron and 18/13 mmHg with hydrochlorothiazide. It was 14/10 mmHg with the placebo.

The average loss of weight was 1·0 kg for the Baycaron group and 1·3 kg for the hydrochlorothiazide group.

The serum sodium decreased by 2·4 m val/litre under Baycaron treatment and 1·0 m val/litre under hydrochlorothiazide.

Serum potassium showed a slight decrease during the treatment with both preparations and the serum urea increased slightly during treatment but the change was not significant.

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TABLE I. RESULTS IN WHITE PATIENTS BEFORE AND AT THE END OF 12 WEEKS' TREATMENT AND IN BANTU PATIENTS BEFORE AND AT THE END OF 2 WEEKS' TREATMENT

	White patients	*Bantu patients*
Average fall in blood pressure (mmHg)		
Baycaron	From 179/105 to 159/97	From 173/114 to 151/98
HCT	From 176/103 to 161/97	From 172/116 to 154/96
Placebo	From 180/104 to 168/94	From 174/113 to 166/103
Average loss of weight (kg)		
Baycaron	1·5	0·5
HCT	1·7	0·9
Placebo	0·5	0·2
Serum sodium (average values) (m val/litre)		
Baycaron	Decrease: 141·1 to 136·9	Decrease: 138·1 to 137·0
HCT	Decrease: 137·9 to 137·2	Decrease: 138·9 to 137·5
Placebo	Increase: 137·5 to 140·1	Decrease: 139·2 to 137·4
Serum potassium (average values) (m val/litre)		
Baycaron	Decrease: 4·37 to 3·87*	Decrease: 4·4 to 4·09
HCT	Decrease: 4·24 to 4·03*	Decrease: 4·9 to 4·5
Placebo	Increase: 4·29 to 4·35	Decrease: 4·4 to 4·3
Serum urea (average values) (mg/100 ml)		
Baycaron	Unchanged	Increase: 28·7 to 30·9
HCT	Unchanged	Increase: 23·9 to 36·9
Placebo	Decrease: 36·9 to 32·7	Increase: 24·5 to 26·5

*There is no statistical difference in the fall in potassium between Baycaron and HCT.