

## MeTK/CLIN/NEB/HYPERTROPHY/03/001

**Sponsor:** I.E. Ulagay Ilac Sanayii Turk A.S.

### **Effects of Nebivolol and Ramipiril on Left Ventricular Hypertrophy, Quality of Life and Blood Pressure in patients with mild to moderate hypertension associated to Left Ventricular Hypertropy (NERVE)**

**Patients and methods:** 132 patients 35-65 y.o. with mild to moderate hypertension and LV Hypertrophy echocardiographically assessed were treated with Nebivolol 5 mg/die and Ramipiril 2.5 mg/die for 39 weeks in this parallel groups, double blind, randomized, phase IV study.

**Objective** This study aimed to compare the effects of Nebivolol versus Ramipiril on Left Ventricular Hypertrophy

**Results:** Both treatments showed a statistically significant effect on systolic and diastolic blood pressure. Heart rate was statistically significantly reduced in Nebivolol treated subjects but not in Ramipiril treated subjects; the reduction of left ventricular mass was statistically significantly more reduced in the Nebivolol treated group as compared to the Ramipiril treated group.

Table 14. Echo data related to Left Ventricular Mass (PP population)

Parameter	Ramipiril (Mean $\pm$ SEM) [n=52]				Nebivolol (Mean $\pm$ SEM) [n=54]				p-value Ramipiril vs. Nebivolol	
	Baseline	39 weeks	$\Delta$	p-value	Baseline	39 weeks	$\Delta$	p-value	At Baseline	At 39 weeks baseline corrected
LVED (mm)	49.49 $\pm$ 0.69	49.07 $\pm$ 0.64	-0.42 $\pm$ 0.32	0.190	49.85 $\pm$ 0.49	48.35 $\pm$ 0.46	-1.50 $\pm$ 0.36	<0.001	0.672	0.029
IVED (mm)	12.52 $\pm$ 0.25	11.52 $\pm$ 0.22	-1.00 $\pm$ 0.17	<0.001	12.75 $\pm$ 0.18	11.11 $\pm$ 0.25	-1.64 $\pm$ 0.16	<0.001	0.435	0.008
LVPWED(mm)	11.86 $\pm$ 0.18	11.06 $\pm$ 0.17	-0.79 $\pm$ 0.16	<0.001	12.19 $\pm$ 0.12	10.70 $\pm$ 0.43	-1.49 $\pm$ 0.17	<0.001	0.120	0.004
LV mass (gram)	279.6 $\pm$ 6.1	247.8 $\pm$ 7.0	-31.8 $\pm$ 5.4	<0.001	293.4 $\pm$ 5.2	230.0 $\pm$ 7.3	-63.4 $\pm$ 6.7	<0.001	0.091	<0.001
LV mass index	146.3 $\pm$ 2.9	130.0 $\pm$ 3.6	-16.4 $\pm$ 2.8	<0.001	148.9 $\pm$ 2.6	117.2 $\pm$ 4.1	-31.7 $\pm$ 3.4	<0.001	0.513	<0.001

**Conclusions:** In the present study it was demonstrated that Nebivolol and Ramipiril show similar results on systolic and diastolic blood pressure during 39 weeks of treatment. However Nebivolol lowered significantly more heart rate as compared to Ramipiril as may be expected. Furthermore Left ventricular Mass and Mass index was significantly reduced after Nebivolol and Ramipiril treatment; in addition the parameters were significantly more reduced in subjects treated with Nebivolol as compared to Ramipiril.