PARADISE-MI

Prospective ARNI vs ACE Inhibitor Trial to Determine Superiority in Reducing Heart Failure Events After MI

Purpose: To evaluate the efficacy and safety of sacubitril/valsartan compared to ramipril on morbidity and mortality in high-risk patients following an AMI.

Trial Design: N=5,669. A multi-center, randomized, double-blind, active-controlled, parallel-group phase 3 study. Sacubitril/valsartan titrated to 200 mg twice daily, compared to ramipril titrated to 5 mg twice daily. Mean follow up 23 months.

Primary Endpoints: Time to first occurrence of a confirmed composite endpoint: CV death, HF hospitalization, or outpatient HF.

Secondary Endpoints: Time to the first occurrence of: CV death or HF hospitalization; HF hospitalization or outpatient HF; CV death, non-fatal MI or non-fatal stroke; recurrent composite endpoints; all cause mortality.

Endpoints	Sacubitril / Valsartan (ARNi) N=2,830	Ramipril (ACEi) N=2,831	HR (95% CI)	p-value
Primary outcome	338 (11.9%)	373 (13.2%)	0.90 (0.78-1.04)	0.17
CV death	168 (5.9%)	191 (6.7%)	0.87 (0.71-1.08)	0.20
HF hospitalization	170 (6%)	195 (6.9%)	0.87 (0.70-1.06)	0.17
Outpatient HF	39 (1.4%)	57 (2%)	0.68 (0.45-1.03)	0.07
CV death or HF hospitalization	308 (10.9%)	335 (11.8%)	0.91 (0.78-1.07)	0.25
HF hospitalization or outpatient HF	201 (7.1%)	237 (8.4%)	0.84 (0.70-1.02)	0.07
CV death, non-fatal MI or non-fatal stroke	315 (11.1%)	349 (12.3%)	0.90 (0.77-1.05)	0.18
CV death and total hospitalizations for HF, MI or stroke	591	682	0.84 (0.70-1.00)	0.045
All-cause death	213 (7.5%)	242 (8.5%)	0.88 (0.73-1.05)	0.16

Results: Sacubitril/Valsartan did not result in a significantly lower rate of CV death, HF hospitalization or outpatient HF.

Results reflect the data available at the time of presentation.

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