

HYVET Trial

The Hypertension in the Very Elderly Trial (HYVET)

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Presented at ACC 2008 in Chicago

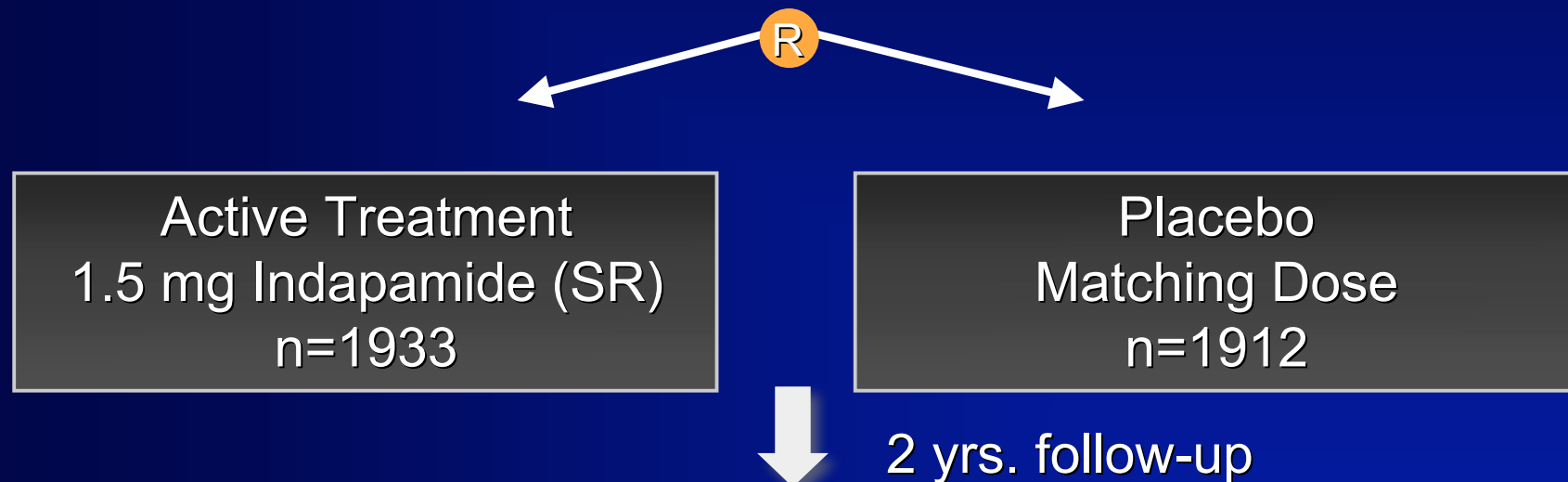
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HYVET Trial: Background

- Blood pressure reduction has been shown to prevent vascular events such as stroke
- There has been no conclusive results suggesting benefit in treating patients with hypertension over 80 years of age
- HYVET's goal was to evaluate the benefits and risks of providing medical care to very elderly individuals presenting with hypertension

HYVET Trial: Study Design

3845 patients \geq 80 years with continual hypertension and systolic blood pressure \geq 160 mm Hg prior to randomization
Prospective. Randomized. Double Blind. Placebo-Controlled. Mean follow-up 1.8yrs



- Primary Endpoint: fatal and non-fatal strokes
- Secondary Endpoints: death from: stroke, cardiovascular causes, cardiac causes and any cause

HYVET Trial: Baseline Characteristics

Characteristic	Active Treatment (n=1933)	Placebo (n=1912)
Age (years \pm SD)	83.6 \pm 3.2	83.5 \pm 3.1
Female (%)	1174 (60.7)	1152 (60.3)
Blood Pressure (mm Hg)		
While sitting		
Systolic	173.0 \pm 8.4	173.0 \pm 8.6
Diastolic	90.8 \pm 8.5	90.8 \pm 8.5
While standing		
Systolic	168.0 \pm 11.0	167.9 \pm 11.1
Diastolic	88.7 \pm 9.3	88.6 \pm 9.3

HYVET Trial: Baseline Characteristics

Characteristic	Active Treatment (n=1933)	Placebo (n=1912)
CV disease (%)	223 (11.5)	229 (12.0)
Hypertension (%)	1737 (89.9)	1718 (89.9)
Antihypertensive Tx (%)	1241 (64.2)	1245 (65.1)
Stroke (%)	130 (6.7)	131 (6.9)
Myocardial Infarction (%)	59 (3.1)	62 (3.2)
Heart Failure (%)	56 (2.9)	55 (2.9)
Current Smoker (%)	123 (6.4)	127 (6.6)
Diabetes (%)	132 (6.8)	131 (6.9)

HYVET Trial: Baseline Characteristics

Characteristic	Active Treatment (n=1933)	Placebo (n=1912)
Total Cholesterol	5.3 ± 1.1	5.3 ± 1.1
HDL-Cholesterol	1.35 ± 0.38	1.35 ± 0.37
Serum Creatinine	88.6 ± 20.5	89.2 ± 20.5
Uric Acid	280.4 ± 79.3	279.0 ± 81.3
Body-Mass Index	24.7 ± 3.8	24.7 ± 3.5
Heart Rate	74.5 ± 9.1	74.5 ± 9.3
Systolic Hypertension (%)	625 (32.3)	623 (32.6)
Orthostatic Hypotension (%)	152 (7.9)	169 (8.8)

HYVET Trial: Outcomes

Main Fatal and Nonfatal End Points in the Intention-to-Treat Population

End Point	Rate per 1000 Patient-Yr (No. of Events)		Unadjusted Hazard Ratio	p-value
	Indapamide	Placebo	(95% CI)	
	No. (%)			
Fatal/nonfatal stroke	12.4 (51)	17.7 (69)	0.70 (0.49-1.01)	0.06
Death from stroke	6.5 (27)	10.7 (42)	0.61 (0.38-0.99)	0.046
Death from any cause	47.2 (196)	59.6 (235)	0.79 (0.65-0.95)	0.02
Death from non-CV/ unknown causes	23.4 (97)	28.9 (114)	0.81 (0.62-1.06)	0.12
Death from CV cause	23.9 (99)	30.7 (121)	0.77 (0.60-1.01)	0.06

HYVET Trial: Outcomes

Main Fatal and Nonfatal End Points in the Intention-to-Treat Population

End Point	Rate per 1000 Patient-Yr (No. of Events)		Unadjusted Hazard Ratio	
	Indapamide	Placebo	(95% CI)	p-value
	No. (%)			
Death from cardiac cause*	6.0 (25)	8.4 (33)	0.71 (0.42-1.19)	0.19
Death from heart failure	1.5 (6)	3.0 (12)	0.48 (0.18-1.28)	0.14
Any fatal or nonfatal MI	2.2 (9)	3.1 (12)	0.72 (0.30-1.70)	0.45
Any fatal or nonfatal heart failure	5.3 (22)	14.8 (57)	0.36 (0.22-0.58)	<0.001
Any fatal or nonfatal cardiovascular event**	33.7 (138)	50.6 (193)	0.66 (0.53-0.82)	<0.001

***Death from cardiac causes was defined as fatal myocardial infarction, fatal heart failure, and sudden death.**Any cardiovascular event was defined as death from cardiovascular causes or stroke, myocardial infarction, or heart failure.**

HYVET Trial: Limitations

- The trial drew upon healthier-than-normal patients, so its data cannot be extrapolated to frailer people
- Evidence to support diagnosis of a stroke was not always available as some patients' deaths were not monitored and an autopsy was not performed

HYVET Trial: Summary

- Lowering the blood pressure of hypertensive patients over the age of 80 is associated with reductions in total mortality and rate of cardiovascular events.