

Management of Acute Pulmonary Hypertensive Crisis in Children With Known Pulmonary Arterial Hypertension

Statistical Analysis Plan

NCT05439460

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For analysis, baseline systolic, diastolic, and mean aortic and pulmonary artery pressures were determined by averaging the data for the 30 seconds immediately prior to the administration of study drug. The peak drug effect was defined as the highest systemic blood pressure and the simultaneous pulmonary artery pressure after administration of study drug. The ratio of systolic pulmonary artery pressure-to-systolic systemic blood pressure was calculated at baseline and peak drug effect.

The primary outcome variable was a change in Rp:Rs after drug administration. Secondary outcomes were the changes in systemic and pulmonary artery pressure, pulmonary artery occlusion pressure, PVR, SVR, and cardiac index after study drug administration.

Statistical comparisons of continuous variables within groups before and after drug administration were made using a paired t test (IBM SPSS Statistics, Armonk, NY); statistical significance was set at a p value of less than 0.05.