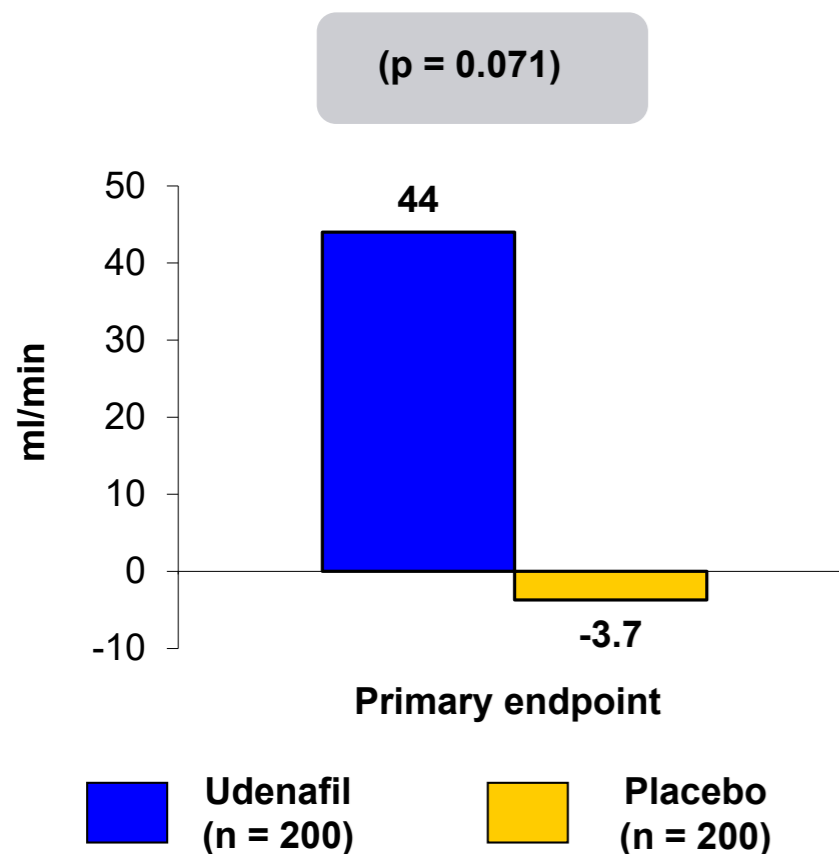


Trial Description: Patients with Fontan physiology were randomized in a 1:1 fashion to either udenafil 87.5 mg BID or placebo. Patients were followed for 26 weeks.



RESULTS

- Primary endpoint, change in peak VO₂ max between baseline and week 26, for udenafil vs. placebo: 44 ml/min (2.8%) vs. -3.7 ml/min (-0.2%), p = 0.071
- Diastolic blood pressure (DBP) change: -2.9 vs. 0.2 mm Hg, p = 0.003
- Oxygen saturation: 0.5% vs. -0.3%, p = 0.002; oxygen consumption at anaerobic threshold: 33 ml/min vs. -9.0 ml/min, p = 0.012

CONCLUSIONS

- Udenafil, a long-acting PDE5 inhibitor, is not superior to placebo in improving oxygen consumption at peak exercise among compensated patients with Fontan physiology
- Improvements were, however, noted in DBP and a few measures of exercise performance at the ventilatory anaerobic threshold