


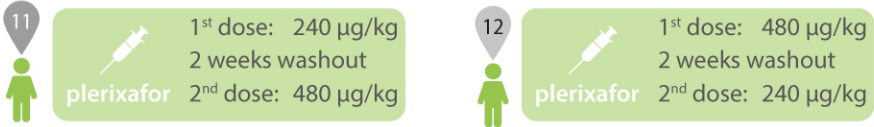


High-dose plerixafor (480 µg/kg) can be safely administered in healthy donors and mobilizes greater numbers of CD34+ cells than conventional-dose plerixafor (240 µg/kg)

 Phase II, open-label, single-center, investigator-initiated, randomized, crossover trial
 23 healthy stem-cell donors
 National Institutes of Health (NIH) Clinical Center in Bethesda, MD, USA



Endpoint	240 µg/kg group (n=11)	480 µg/kg group (n=12)	p-value
Primary endpoint			
peak CD34+ count in the blood (cells/µL)	27.8	32.2	p=0.0009
Secondary endpoints			
CD34+ cell area under the curve over 24 hours (h cells/µL)	446	553	p<0.0001
CD34+ count at 24 hours (cells/µL)	10.7	17.8	p<0.0001
time to peak CD34+ (hours)	8.4	10.5	p=0.012

7 subjects mobilized poorly (peak CD34+ ≤ 20 cells/µL) but after the 480 µg/kg dose

- 6/7 achieved higher peak CD34+ cell numbers
- 7/7 achieved higher CD34+ AUCs over 24 hours