

Sample size

Estimated sample size for two sample comparison of means, using the formula below:

$$\frac{(u+v)^2 (\sigma_1^2 + \sigma_2^2)}{(\mu_1 - \mu_2)^2}$$

Test Ho: $\mu_1 = \mu_2$

Assumptions:

Power 90%: $u = 1.28$

Alpha 0.05 (2 sided): $v = 1.96$

Based on the study done by Cojocaru et al*

$\mu_1 = 6.8$; $\sigma_1 = 3.8$ (mean and standard deviation respectively, of the total number of stools over the 1st 48 hours in the intervention arm)

$\mu_2 = 9.5$; $\sigma_2 = 4.5$ (mean and standard deviation respectively, of the total number of stools over the 1st 48 hours in the control arm)

Cojucaru et al selected subjects as they came in for treatment over the period of sample collection. There was no formal sample size calculation presented in their paper.

$N_2/N_1 = 1.0$

Calculated sample size each arm: 51

Estimated for loss 10%

Final sample Size: 60 in each arm

* Cojocaru B, Bocquet N, Timsit S, et al. Effect of racecadotril in the management of acute diarrhea in infants and children. Archives of pediatrics. 2002; 8:774 - 9.