

Sample size for a given precision: An Example

Specific Aims

- Pilot study of silver alginate-containing dressings for central catheter in neonatal intensive care patients
- Aims: Evaluate the safety and effectiveness of new dressing
 1. To test the hypothesis that silver alginate-containing dressings on peripherally inserted central catheters (PICC) are safe.
 2. To test the hypothesis that silver alginate-containing dressings are effective in reducing PICC associated blood stream infections in NICU patients.

Study Design

- Randomize patients to Treatment or Control groups
- Specific eligibility criteria

Background

- Preliminary data (from Baylor) did not report any adverse skin findings
- In our preliminary analysis, so far we also have not observed any evidence for skin hypersensitivity reactions or skin color changes
- We estimate that a total of at least 100 patients can be enrolled into the study during the 3-month pilot period
- In 2007, 550 PICC were placed at the Vanderbilt NICU. A total of 70 PICC infections were registered (12.7%)

Sample Size

- Randomly assign 100 subjects to the treatment or control groups in a 3:1 ratio
 - Use a random number generator where subjects are three

- times more likely to be assigned to the treatment group
- The unbalanced design will allow us to estimate the infection percentage and adverse event rates with more precision in the treatment group.
 - With 75 treatment subjects, the margin of error (half the confidence interval width) for estimating the percentage with infections will be +/- 6%
 - The margin of error for estimating any adverse events will not be larger than +/- 10%
 - If we do not observe a particular adverse event, we will be 95% confident that that event rate is less than 4% (3/n rule)
- Assuming the infection percentage decrease to 6% on treatment
 - The power to detect a significant difference between the treatment and control group using a 3:1 randomization design is 23%
 - A balanced 1:1 design has similar power (21%).

Future Studies

- This pilot study has limited power to detect a significant difference between treatment and control groups
- May indicate that a larger study is warranted
- If infections drop to 6% in the treatment group
 - A study with 296 subjects in each group would have 80% power
 - A study with 395 subjects in each group would have 90% power.