Sample size re-estimation in an on-going NIH-sponsored clinical trial: the secondary prevention of small subcortical strokes experience.

Published by lmcclore on Mon, 08/19/2013 - 12:56pm

**Title**
Sample size re-estimation in an on-going NIH-sponsored clinical trial: the secondary prevention of small subcortical strokes experience.

**Publication Type**
Journal Article

**Year of Publication**
2012

**Authors**
McClure, LA, Szychowski, JM, Benavente, O, Coffey, CS

**Journal**
Contemp Clin Trials

**Volume**
33

**Issue**
5

**Pagination**
1088-93

**Date Published**
2012 Sep

**ISSN**
1559-2030

**Keywords**
Blood Pressure, Humans, National Institutes of Health (U.S.), Platelet Aggregation Inhibitors, Randomized Controlled Trials as Topic, Sample Size, Secondary Prevention, Stroke, United States

**Abstract**

BACKGROUND AND PURPOSE: When planning clinical trials, decisions regarding sample size are often based on educated guesses of parameters, which may in fact prove to be over- or under-estimates. For example, after initiation of the SPS3 study, published data indicated that the recurrent stroke rates might be lower than initially planned for the study. Failure to account for this could result in an under-powered study. Thus, we performed a sample size re-estimation, and describe the experience herein.

METHODS: We evaluated different scenarios based on a re-estimated overall event rate, including increasing the sample size and increasing the follow-up time, to determine their impact on both type I error and the power to detect the initially planned treatment difference.

RESULTS: We found that by increasing the sample size from 2500 to 3000 and by following the patients for one year after the end of recruitment, we would maintain our planned type I error rate, and increase the power to detect the prespecified clinically meaningful difference to between 67% and 87%, depending on the rate of recruitment.

CONCLUSIONS: We successfully implemented this unplanned design modification in the SPS3 study, in order to allow for sufficient power to detect the planned treatment differences.

**CLINICAL TRIALS REGISTRATION**