

Statistical significance needs to be distinguished from clinical significance. Kaul and Diamond (63) Kane (64) Bhardwaj et al. (65) and Houle and Stump (66) warn of the situation where data are statistically significant but are not clinically significant and have no real-world value. A number of publications have reported that a parameter was statistically significant, but not clinically significant, for example Jeffrey et al. (67) and van Maldegem et al. (68). Fethney (69) pointed out that the P value on its own provides no information about the overall importance or meaning of the results to clinical practice.

IX. CALCULATING THE P VALUE – A WORKING EXAMPLE

Table 9.2 lists the parameters needed for calculating the P value.

Only one example will be shown for calculating the P value. This example involves comparing the mean of a first sample (study drug group) with the mean of a second sample (control group). The data are from Machin and Gardner (70).

In Group 1 (study drug group), subjects died on months: 6, 6, 10, 10, 12, 12, 12, 12, 24, and 32.

In Group 0 (control group), subjects died on months: 6, 6, 6, 6, 8, 8, 12, 12, 20, 24, 30, and 42.

When faced with the need to calculate a P value, the researcher must choose between various different statistical tests. One of these tests involves an intermediate step where the *Z* statistic is calculated, while another commonly used test has an intermediate step where the *t* statistic is calculated. According to Pocock (71) the simplest test is the one using the *Z* statistic. But it should be noted that calculations using the *Z* statistic may be misleading when analyzing small samples, and that the *t* statistic is more appropriate with small samples (72). With large samples the *t* statistic and *Z* statistic are equivalent to each other (73).

⁶³ Kaul S, Diamond GA. Trial and error. How to avoid commonly encountered limitations of published clinical trials. *J Am Coll Cardiol*. 2010;55:415–427.

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⁶⁵ Bhardwaj SS, Camacho F, Derrow A, Fleischer Jr AB, Feldman SR. Statistical significance and clinical relevance: the importance of power in clinical trials in dermatology. *Arch Dermatol*. 2004;140:1520–1523.

⁶⁶ Houle TT, Stump DA. Statistical significance versus clinical significance. *Semin. Cardiothorac. Vasc Anesth*. 2008;12:5–6.

⁶⁷ Jeffery NN, Douek N, Guo DY, Patel MI. Discrepancy between radiological and pathological size of renal masses. *BMC Urol*. 2011;11(2):9.

⁶⁸ van Maldegem BT, Duran M, Wanders RJ, et al. Clinical, biochemical, and genetic heterogeneity in short-chain acyl-coenzyme A dehydrogenase deficiency. *J Am Med Assoc*. 2006;296:943–952.

⁶⁹ Fethney J. Statistical and clinical significance, and how to use confidence intervals to help interpret both. *Aust Crit Care*. 2010;23:93–97.

⁷⁰ Machin D, Gardner MJ. Calculating confidence intervals for survival time analyses. *Brit Med J*. 1988;296:1369–1371.

⁷¹ Pocock SJ. The simplest statistical test: how to check for a difference between treatments. *Brit Med J*. 2006; 332:1256–1258.

⁷² Motulsky H. E-mail of May 9, 2011.

⁷³ Motulsky H. E-mail of May 9, 2011.