



Description of tests used to evaluate clinical data

There are two tests that are useful in situations where we are comparing the means of two different populations (placebo vs. active). There are slight technical differences between them and either one would have been adequate. The utilization of both tests was only to "double check" that we did in fact receive statistically significant results.

T-test for equality of means, or student's T-test – Assesses whether the means (averages) of two groups are statistically different from each other. It assumes that the two populations are otherwise similar.

Mann-Whitney is a test which determines whether or not two independent groups are significantly different. It can be thought of as testing the null hypothesis (hypothesis set up to be nullified or refuted. It is presumed true until statistical evidence proves otherwise) that the probability of an observation from one population exceeding an observation from the second population is 0.5. This (null) hypothesis will be refuted if the probability of such an occurrence is found to be less than 0.5, and then it is assumed that the results from the two population samples are truly distinct one from the other.

Probability (p-value) and statistical significance threshold (alpha level)

This is the probability of a false-positive error. This means, that the drug appears to be better than placebo, but it really is not and the result occurred by chance. For example, a p-value of .01 ($p = .01$) means there is a 1 in 100 chance the result occurred by chance. The alpha level is the threshold for defining statistical significance (anything above the defined alpha level will be considered insignificant, or not a true difference between placebo and treatment). We have defined it as <0.5 , meaning that there must be a less than 1 in 500 chance that the results (advantage of drug over placebo) occurred by chance. As can be understood, the higher the p-value (tested by either of the two tests mentioned above), the higher the probability that the results occurred by chance, and visa-versa.

The Standard Deviation is a measure of the dispersion of random errors about the mean value. The greater the standard deviation, the greater the range of values within the sample.