



### 3 Primary Scientific Question

Is the expected power level as assessed prior to a study in agreement with the power level obtained.

### 4 Data Example

The expected power of a study of a 10 patient crossover study is 90 %. The results of the study are given underneath:

observation 1:

6.0, 7.1, 8.1, 7.5, 6.4, 7.9, 6.8, 6.6, 7.3, 5.6

observation 2:

5.1, 8.0, 3.8, 4.4, 5.2, 5.4, 4.3, 6.0, 3.7, 6.2

Individual differences

0.9, -0.9, 4.3, 3.1, 1.2, 2.5, 2.5, 0.6, 3.8, -0.6

Is there a significant difference between the observation 1 and 2, and which level of significance is correct?

Mean difference = 1.59

SD of mean difference = 1.789

SE =  $SD/\sqrt{10}$  = 0.566

$t = 1.59/0.566$  = 2.809

$10 - 1 = 9$  degrees of freedom (10 patients and 1 group of patients).

Look at the underneath t-table to find the p-value, and assess the presence of superiority.

## 5 T-Table

df	One-Tail = .4	.25	.1	.05	.025	.01	.005	.0025	.001	.0005
	Two-Tail = .8	.5	.2	.1	.05	.02	.01	.005	.002	.001
1	0.325	1.000	3.078	6.314	12.706	31.821	63.657	127.32	318.31	636.62
2	0.289	0.816	1.886	2.920	4.303	6.965	9.925	14.089	22.327	31.598
3	0.277	0.765	1.638	2.353	3.182	4.541	5.841	7.453	10.214	12.924
4	0.271	0.741	1.533	2.132	2.776	3.747	4.604	5.598	7.173	8.610
5	0.267	0.727	1.476	2.015	2.571	3.365	4.032	4.773	5.893	6.869
6	0.265	0.718	1.440	1.943	2.447	3.143	3.707	4.317	5.208	5.959
7	0.263	0.711	1.415	1.895	2.365	2.998	3.499	4.029	4.785	5.408
8	0.262	0.706	1.397	1.860	2.306	2.896	3.355	3.833	4.501	5.041
9	0.261	0.703	1.383	1.833	2.262	2.821	3.250	3.690	4.297	4.781
10	0.260	0.700	1.372	1.812	2.228	2.764	3.169	3.581	4.144	4.587
11	0.260	0.697	1.363	1.796	2.201	2.718	3.106	3.497	4.025	4.437
12	0.259	0.695	1.356	1.782	2.179	2.681	3.055	3.428	3.930	4.318
13	0.259	0.694	1.350	1.771	2.160	2.650	3.012	3.372	3.852	4.221
14	0.258	0.692	1.345	1.761	2.145	2.624	2.977	3.326	3.787	4.140
15	0.258	0.691	1.341	1.753	2.131	2.602	2.947	3.286	3.733	4.073
16	0.258	0.690	1.337	1.746	2.120	2.583	2.921	3.252	3.686	4.015
17	0.257	0.689	1.333	1.740	2.110	2.567	2.898	3.222	3.646	3.965
18	0.257	0.688	1.330	1.734	2.101	2.552	2.878	3.197	3.610	3.922
19	0.257	0.688	1.328	1.729	2.093	2.539	2.861	3.174	3.579	3.883
20	0.257	0.687	1.325	1.725	2.086	2.528	2.845	3.153	3.552	3.850
21	0.257	0.686	1.323	1.721	2.080	2.518	2.831	3.135	3.527	3.819
22	0.256	0.686	1.321	1.717	2.074	2.508	2.819	3.119	3.505	3.792
23	0.256	0.685	1.319	1.714	2.069	2.500	2.807	3.104	3.485	3.767
24	0.256	0.685	1.318	1.711	2.064	2.492	2.797	3.091	3.467	3.745
25	0.256	0.684	1.316	1.708	2.060	2.485	2.787	3.078	3.450	3.725
26	0.256	0.684	1.315	1.706	2.056	2.479	2.779	3.067	3.435	3.707
27	0.256	0.684	1.314	1.703	2.052	2.473	2.771	3.057	3.421	3.690
28	0.256	0.683	1.313	1.701	2.048	2.467	2.763	3.047	3.408	3.674
29	0.256	0.683	1.311	1.699	2.045	2.462	2.756	3.038	3.396	3.659
30	0.256	0.683	1.310	1.697	2.042	2.457	2.750	3.030	3.385	3.646
40	0.255	0.681	1.303	1.684	2.021	2.423	2.704	2.971	3.307	3.551
60	0.254	0.679	1.296	1.671	2.000	2.390	2.660	2.915	3.232	3.460
120	0.254	0.677	1.289	1.658	1.980	2.358	2.617	2.860	3.160	3.373
∞	0.253	0.674	1.282	1.645	1.960	2.326	2.576	2.807	3.090	3.291

The t-table has a left-end column giving degrees of freedom ( $\approx$  sample sizes), and two top rows with p-values (areas under the curve = p – values), one-tail meaning that only one end of the curve, two-tail meaning that both ends are assessed simultaneously. The t-table is, furthermore, full of t-values, that, with  $\infty$  degrees of freedom, are equal to z-values (Chap. 36). The t-values are to be understood as mean results of studies, but not expressed in mmol/l, kilograms, but in so-called SEM-units (Standard error of the mean units), that are obtained by dividing your mean result by its own standard error. With many degrees of freedom (large samples) the curve will be a little bit narrower, and more in agreement with nature.

The ninth row of t-values shows that our t-value is between 2.262 and 2.821. This would mean a p-value between 0.05 and 0.02. There is, thus, a significant difference between observation 1 and 2. However, is the expected power obtained or is this study underpowered. The t-table is helpful to calculate the t-value required for a power of 90 %: it mean a beta-value (type II error value) of 10 % (= 0.1). Look at the upper row of the t-table.

If  
 beta = 0.1, then  
 $z_{\text{beta}}$  for 9 degrees of freedom  
 = 1.383.

The t-value required for a power of 90 %  
 =  $1.383 + t^1$ , where  $t^1$  is the 0.05  
 =  $1.383 + 2.262$   
 = 3.645.

The required t-value is much larger than the obtained t-value of 2.809, and, so, the study does not meet its expected power. The treatment is less efficaceous than expected.

If the investigators had required a power of 60 %, then the superiority testing would be as follows.

beta = 0.40  
 z = 0.261

The t-value required for a power of 60 %  
 =  $0.261 + t^1$ , where  $t^1$  is the 0.05  
 =  $0.261 + 2.262$   
 = 2.523.

This t-value is smaller than the obtained t-value of 2.809, and, so, the study would have met an expected power of 60 %.

## 6 Conclusion

Superiority testing of a study means testing whether the study meets its a priori defined expected power. Many therapeutic studies may be able to reject their null-hypotheses, and, are, thus, statistically significant, but they do not meet their expected power. Superiority testing assesses whether the eventual power of a study is in agreement with the power as stated in the sample size calculation of the study. This chapter shows that with the help of the t-table the presence of superiority can be readily assessed.

We should note that the terms z-value and t-values are often used interchangeably, but strictly the z-value is the test statistic of the z-test, and the t-value is the test statistic of the t-test. The bottom row of the t-table is equal to the z-table.

## **7 Note**

More background, theoretical and mathematical information, and alternative approaches to superiority testing is given in *Statistics applied to clinical studies* 5th edition, Chap. 62, Springer Heidelberg Germany, 2012, from the same authors.