Chapter 6
Equivalence Tests

Equivalence testing is important, if you expect a new treatment to be equally efficaceous as the standard treatment. This new treatment may still be better suitable for practice, if it has fewer adverse effects or other ancillary advantages.

For the purpose of equivalence testing we need to set boundaries of equivalence prior to the study. After the study we check whether the 95% confidence interval of the study is entirely within the boundaries.

As an example, in a blood pressure study a difference between the new and standard treatment between −10 and +10 mm Hg is assumed to smaller than clinically relevant. The boundary of equivalence is, thus, between −10 and +10 mm Hg. This boundary is a priori defined in the protocol.

Then, the study is carried out, and both the new and the standard treatment produce a mean reduction in blood pressure of 10 mm Hg (parallel-group study of 20 patients) with standard errors 10 mm Hg.

$$\begin{aligned}\text{The mean difference} &= 10 - 10 \text{ mm Hg}\\ &= 0 \text{ mm Hg}\end{aligned}$$

$$\text{The standard errors of the mean differences} = 10 \text{ mm Hg}$$

$$\begin{aligned}\text{The pooled standard error } (n = 10) &= \sqrt{(100/10 + 100/10)} \text{ mm Hg}\\ &= \sqrt{20} \text{ mm Hg}\\ &= 4.47 \text{ mm Hg}\end{aligned}$$

$$\begin{aligned}\text{The 95\% confidence interval of this study} &= 0 \pm 2 \times 4.47 \text{ mm Hg}\\ &= \text{between } -8.94 \text{ and } +8.97 \text{ mm Hg}\end{aligned}$$

This result is entirely within the a priori defined boundary of equivalence, which means that equivalence is demonstrated in this study.

T.J. Cleophas and A.H. Zwinderman, *Statistical Analysis of Clinical Data on a Pocket Calculator: Statistics on a Pocket Calculator*, DOI 10.1007/978-94-007-1211-9_6,