**The Problem**

A clinical trial was conducted to compare a new blood pressure-lowering medication to a placebo. Patients were enrolled and randomized to receive either the new medication or placebo. The data below were collected at the end of the 6 week study.

|  |  |  |
| --- | --- | --- |
|  | **Treatment (n=100)** | **Placebo (n=100)** |
| Systolic Blood Pressure, mean (sd) | 120.2 (15.4) | 131.4 (18.9) |
| Hypertensive, % | 14% | 22% |
| Side Effects, % | 6% | 8% |

Generate a point estimate and 95% confidence interval for the risk ratio of side effects in patients assigned to the experimental group as compared to placebo. Use both the hand calculation method and the method using R to see if you get the same answers. Interpret the results in a sentence or two.

**Answer:**

First, we created a contingency table with the counts (based on the % and n), and we oriented it in a way that can be used for R.

|  |  |  |  |
| --- | --- | --- | --- |
|  | **No Side Effects** | **Side Effects**  | **Total** |
| Placebo | 92 | 8 | 100 |
| New drug | 94 | 6 | 100 |

 RR=0.06/0.08 = 0.75

In R:

> log(0.75)

[1] -0.2876821

We then calculated the 95% CI for ln(RR):

$$-0.29\pm \sqrt{\frac{\left(1-0.06\right)}{6}+\frac{\left(1-0.08\right)}{8}}= -0.29\pm 1.02=(-1.31, 0.73)$$

Then we exponentiated the log limits to get the 95% CI for RR:

(e-1.31, e0.73) = (0.27,2.08)

Next we repeated the entire analysis in R.

> RRtable<-matrix(c(92,94,8,6),nrow = 2, ncol = 2)

> RRtable
     [,1] [,2]
[1,]   92    8
[2,]   94    6
> riskratio.wald(RRtable)
$data
          Outcome
Predictor  Disease1 Disease2 Total
 Exposed1       92        8   100
 Exposed2       94        6   100
 Total         186       14   200

$measure
 risk ratio with 95% C.I.
 Predictor  estimate     lower    upper
 Exposed1      1.00        NA
 Exposed2      0.75 0.2700231 2.083155

$p.value
 two-sided
 Predictor  midp.exact fisher.exact chi.square
 Exposed1          NA
 Exposed2  0.5947856     0.7828074  0.5793913

$correction
[1] FALSE

attr(,"method")

[1] "Unconditional MLE & normal approximation (Wald) CI"

 ***Interpretation:*** Those on the new drug had 0.75 times the risk of side effects compared to the placebo group over the six week observation period (p=0.58). With 95% confidence the true risk ratio lies in the range of 0.27 to 2.08. Since the confidence interval includes a risk ratio of 1, the results are not statistically significant, and this is also indicated by the p-value=0.58.