A Phase III trial examined the effectiveness of a new treatment (T) versus active control (C) in patients with head lice. Randomization to treatment is to be carried out in a 1:1 manner. Patients are to be given the treatment for one day and are to be checked once to see if the head lice still exists (a yes/no dichotomous outcome) 21 days after treatment. The main objective of the trial is to show that T is not inferior to C with respect to the proportion of patients who still have head lice 21 days after treatment. Assume the true control group head lice rate after 21 days is 0.40 (40%).

H_0: $\pi_T - \pi_C \geq 0.15$ The new treatment is inferior to the control treatment.
H_A: $\pi_T - \pi_C < 0.15$ The new treatment is not inferior to the control treatment.

A sample size of 332, 166 per group, yields 80% power to detect a risk difference margin of 15% in proportion of head lice, using a 1:1 allocation ratio while assuming risk of 40% in the treatment and active control group.

$$\frac{\pi_T}{\pi_C} \geq \frac{\pi_T + \delta}{\pi_C}$$
$$\frac{\pi_T}{\pi_C} \geq \frac{0.4 + 0.15}{0.4}$$
$$\frac{\pi_T}{\pi_C} \geq 1.375$$

H_0: $\frac{\pi_T}{\pi_C} \geq 1.375$ The new treatment is inferior to the control treatment.
H_A: $\frac{\pi_T}{\pi_C} < 1.375$ The new treatment is not inferior to the control treatment.

A sample size of 472, 236 per group, yields 80% power to detect a relative risk margin of 15% in proportion of remaining head lice, using a 1:1 allocation ratio while assuming risk of 40% in the treatment and active control group. This required sample size using the RR method is larger than using the RD method, which is expected because the outcome of interest is negative.

Suppose that after the study is over, 131 of 227 patients in the new drug group still had head lice after 21 days as compared to 100 of 217 patients in the active group.

H_0: $\pi_C - \pi_T \leq -0.15$ The new treatment is inferior to the control treatment.
H_A: $\pi_C - \pi_T > -0.15$ The new treatment is not inferior to the control treatment.

$RD = -0.1163$ (95% confidence interval: -0.2086, -0.0240)

The p-value was 0.2360, which is greater than the α=0.025 significance level. The lower bound of the 95% confidence interval, -0.2086, is less than the non-inferiority margin, -0.15. The null hypothesis of the new treatment being inferior to the active control treatment cannot be rejected. There is insufficient evidence to support that the new treatment is not inferior or just as good as the active control.

$$\frac{\pi_T}{\pi_C} \geq \frac{\pi_T + \delta}{\pi_C}$$
$$\frac{\pi_T}{\pi_C} \geq \frac{0.4 + 0.15}{0.4}$$
$$\frac{\pi_T}{\pi_C} \geq 1.375$$

$$\frac{\pi_C}{\pi_T} \geq \frac{0.4}{0.4 + 0.15}$$
$$\frac{\pi_C}{\pi_T} \geq 0.7273$$

H_0: $\frac{\pi_C}{\pi_T} \geq 0.7273$ T is inferior to C
H_A: $\frac{\pi_C}{\pi_T} < 0.7273$ T is not inferior to C

$RR = 0.7985$ (95% confidence interval: 0.6637, 0.9564)

The p-value was 0.1588, which is greater than the α=0.025 significance level. The lower bound of the 95% confidence interval, 0.6637, is less than the non-inferiority margin, 0.7273. The null hypothesis of the new treatment being inferior to the active control treatment cannot be rejected. There is insufficient evidence to support that the new treatment is not inferior or just as good as the active control.