BS 851

Homework 9

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**Part A**

H0: T is inferior to C

HA: T is not inferior to C

The outcome, proportion still having head lice, is a negative outcome.

**Part B**

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.

**Part C**

H0: T is inferior to C

HA: T is not inferior to C

**Part D**

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 method is larger than using the method, which is expected because the outcome of interested is negative.

**Part E**

Non-inferiority is not achieved in this trial using a risk difference margin of 0.15.

Part i)

H0: T is inferior to C

HA: T is not inferior to C

Part ii)

(95% confidence interval: -0.2086, -0.0240)

Part iii)

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.

**Part F**

Part i)

H0: T is inferior to C

HA: T is not inferior to C

Part ii)

(95% confidence interval: 0.6637, 0.9564)

Part iii)

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.