BS 851

Homework 4

Irene Hsueh

**Question 1**

H0: . The change in SBP is the same for both treatment and placebo groups.

HA: . The change in SBP is not the same in treatment and placebo groups.

**Question 2**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Demographics | | **Treatment Group**  (n=22) | **Placebo Group**  (n=24) | **Total**  (n=46) |
| **Sex** no. (%) | Male | 13 (59.1%) | 15 (64.5%) | 28 (60.9%) |
| Female | 9 (41.0%) | 9 (37.5%) | 18 (39.1%) |
| **Site** no. (%) | 1 | 3 (13.6%) | 7 (29.2%) | 10 (21.7%) |
| 10 | 7 (31.8%) | 3 (12.5%) | 10 (21.7%) |
| 50 | 12 (54.6%) | 14 (58.3%) | 26 (56.5%) |
| **Hypertension** no. (%) | No | 15 (68.2%) | 11 (45.8%) | 26 (56.5%) |
| Yes | 7 (31.8%) | 13 (54.2%) | 20 (43.5%) |
| **Base SBP**  mean (stdv) | | 173.2 (17.6) | 175.7 (18.5) | 174.5 (17.9) |
| **SBP Change**  mean (stdv) | | -29.8 (15.6) | -16.8 (18.5) | -23.0 (18.2) |

**Question 3**

An ANOVA test was used to test whether the change in a subject’s systolic blood pressure was linearly associated with treatment group and study center. The F-statistic was 2.42 and resulting p-value was 0.0793. With a p-value greater than the α=0.05 significance level, the null hypothesis of there being no linear association between change in systolic blood pressure and the predictor variables was not rejected. There is insufficient evidence to conclude a linear association between a change in systolic blood pressure and either treatment group or study center.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Parameter** | | **Estimate** | **p-value** | **95% Confidence Interval** | |
| **Upper Limit** | **Lower Limit** |
| Intercept | | -12.69 |  |  |  |
| Treatment Group | Treatment | -12.35 | 0.0252 | -23.09 | -1.61 |
| Placebo |  |  |  |  |
| Center | Site 10 | -4.26 | 0.5999 | -20.52 | 12.00 |
| Site 50 | -6.18 | 0.3487 | -19.35 | 6.98 |
| Site 1 |  |  |  |  |

A multiple linear regression analysis was used to test whether the change in systolic blood pressure was the same for both treatment and placebo groups, adjusting for study center. The F-statistic was 5.38 and resulting p-value was 0.0252. With a p-value less than the α=0.05 significance level, the null hypothesis of there being no difference in systolic blood pressure change between treatment groups was rejected. There is evidence suggesting that among participants in the same study center, those in the treatment group had a 12.35 mmHg greater decrease in systolic blood pressure than those in the placebo group. The confidence interval for the outcome variable does not include 0, which indicates a statistically significant difference between the two groups, which is the same conclusion from the multiple linear regression analysis.

**Question 4**

An ANCOVA test was used to test whether the change in a subject’s systolic blood pressure was linearly associated with treatment group, study center, and baseline systolic blood pressure. The F-statistic was 3.49 and resulting p-value was 0.0153. With a p-value less than the α=0.05 significance level, the null hypothesis of there being no linear association between change in systolic blood pressure and the predictor variables was rejected.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Parameter** | | **Estimate** | **p-value** | **95% Confidence Interval** | |
| **Upper Limit** | **Lower Limit** |
| Intercept | | 45.06 |  |  |  |
| Treatment Group | Treatment | -13.33 | 0.0117 | -23.54 | -3.12 |
| Placebo |  |  |  |  |
| Center | Site 10 | -3.27 | 0.6711 | -18.70 | 12.16 |
| Site 50 | -5.27 | 0.3997 | -17.76 | 7.23 |
| Site 1 |  |  |  |  |
| baseline SBP | | -0.33 | 0.0200 | -0.61 | -0.06 |

A multiple linear regression analysis was used to test whether the change in systolic blood pressure was the same for both treatment and placebo groups, adjusting for study center and baseline systolic blood pressure. The F-statistic was 6.96 and resulting p-value was 0.0117. There is evidence suggesting that among participants in the same study center and with the same baseline systolic blood pressure, those who received the experimental treatment had a 13.33 greater decrease in systolic blood pressure than those in the placebo group. The confidence interval for the outcome variable does not include 0, which indicates a statistically significant difference between the two groups, which is the same conclusion from the multiple linear regression analysis.

The increase in significance from the ANOVA test is due to baseline SBP and reduction in SBP having a Pearson correlation coefficient of -0.3079, indicating a moderate correlation between the two variables. Adjusting for baseline covariates that are found to be correlated with the outcome variable of interest gives more precise treatment effect estimates.

**Question 5**

The intercept, 45.06, is the average decrease in SBP for those in the placebo group at site 1 when the baseline SBP is 0.

The treatment effect, -13.33, is the difference in SBP decrease between treatment and placebo groups for those at the same study center and same baseline SBP.

The parameter for Site 10, -3.27, is the difference in SBP decrease between those at Site 10 and those at Site 1 for subjects in the same treatment group with the same baseline SBP.

The parameter for Site 50, -5.27, is the difference in SBP decrease between those at Site 50 and those at Site 1 for subjects in the same treatment group with the same baseline SBP.

The parameter for baseline SBP, -0.33, is the difference in SBP decrease for every 1 mmHg increase in baseline SBP for those in the same treatment group and study center.

**Question 6**

The study can be considered successful because the experimental treatment decreased SBP by an additional 13.33 mmHg than the placebo did, adjusting for study center and baseline SBP.

**Question 7**

H0: . . The odds of having hypertension at the end of the study is the same in both treatment groups.

HA: . . The odds of having hypertension at the end of the study is not the same in both treatment groups.

**Question 8**

A multiple logistic regression analysis was used to test whether having hypertension at the end of the study was linearly associated on the natural logarithmic scale with treatment group and study center. From the likelihood ratio test, the chi-squared statistic was 4.5698 with 3 degrees of freedom and the resulting p-value was 0.2062. With a p-value greater than the α=0.05 significance level, the null hypothesis of there being no linear association between having hypertension and the two regressors was not rejected. There is insufficient evidence suggesting that there is a linear association on the natural logarithmic scale between having hypertension at the end of the study and the two predictor variables, treatment group and study center.

A Wald test was used to test whether having hypertension at the end of the study was linearly associated on the logarithmic scale with treatment group, adjusting for study center. The Wald chi-squared statistic was 2.3444 with 1 degree of freedom and the resulting p-value was 0.1257. With a p-value greater than the α=0.05 significance level, the null hypothesis of there being no linear association on the natural logarithmic scale between having hypertension at the end of the study and treatment group, adjusting for study center was not rejected. There is insufficient evidence the suggest the experimental drug is more efficient at reducing the percentage of individuals with hypertension. The study cannot be considered a success on this outcome.

**Question 9**

If it is known that baseline SBP is correlated with hypertension, then it should be included in the final model. Adjusting for covariates that are correlated with the outcome of interest will give a less precise treatment effect estimate.