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Q1. Table

| Number | Study Groups | |
|---|---|---|
| | New Drug | Placebo |
| Patients randomized | 170 | 180 |
| withdraw from study | 75 | 70 |
| # of develop diabetes | 10 | 15 |
| Compliers who develop diabetes | 4 | 8 |
| ITT | $\frac{10}{170} = 5.88\%$ | $\frac{15}{180} = 8.33\%$ |
| PP | $\frac{4}{170-75} = 4.21\%$ | $\frac{8}{180-70} = 7.27\%$ |

Formula
$$\begin{cases} Z = (P_1 - P_2) / Se\{P_1 - P_2\} \\ Se\{P_1-P_2\} = \sqrt{P(1-P)(\frac{1}{n_1}+\frac{1}{n_2})} \end{cases}$$
$$P = (a+b)/(n_1+n_2)$$

For ITT Analysis: $\begin{cases} H_0: \pi_1 = \pi_2 \\ H_a: \pi_1 \neq \pi_2 \end{cases}$ where $\pi_1$ and $\pi_2$ are the population proportions for the drug and placebo group respectively

In this case: $p_1 = 5.88\%$ $p_2 = 8.33\%$ $n_1 = 170$ $n_2 = 180$

$a = 10$ $b = 15$ $p = (a+b)/(n_1+n_2) = 0.07143$

$$Se\{p_1 - p_2\} = \sqrt{0.07143(1-0.07143)(\frac{1}{170}+\frac{1}{180})} = 0.0275$$

$$Z = (P_1 - P_2)/Se\{P_1 - P_2\} = -0.891$$

$$\alpha = 0.01 \Rightarrow Z_{1-\frac{\alpha}{2}} = Z_{0.995} = 2.575$$

$\Rightarrow$ RR (reject region): $|Z| > Z_{1-\frac{\alpha}{2}}$

since $|Z| = |-0.891| = 0.891 < Z_{1-\frac{\alpha}{2}}$

then we conclude $H_0$, the treatment effect of ITT Study is not significant.

For PP Analysis : $H_0: \pi_1 = \pi_2$ vs $H_a: \pi_1 \neq \pi_2$ $P_1 = 4.21\%$ $P_2 = 7.27\%$

$n_1 = 95$ $n_2 = 110$ $a = 4$ $b = 8$ $p = (4+8)/(195+110) = 0.0585$

$Se\{P_1 - P_2\} = \sqrt{0.0585 \times (1-0.0585)(\frac{1}{95} + \frac{1}{110})} = 0.03287$

$Z = (P_1 - P_2)/Se\{P_1 - P_2\} = -0.931$

RR: $|Z| > Z_{1-\frac{\alpha}{2}} = Z_{0.995} = 2.575$

for $|Z| = |-0.931| = 0.931 < Z_{1-\frac{\alpha}{2}}$

we conclude $H_0$, the treatment effect of PP study is not significant.

for $|Z_{ITT\ obs}| = 0.891 < |Z_{PP\ obs}| = 0.931$

we conclude the treatment effect of ITT studys is worse than PP study

Q2. ITT study : P-value = 0.3734 $> 0.01$

PP Study : P-value = 0.3524 $> 0.01$

They are both nonsignificant, since P-value(pp) < P-value(ITT), PP study is better.

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Q3 formula $\begin{cases} Z = \dfrac{\log OR}{SE\{\log OR\}} \\ OR = \dfrac{a/c}{b/d} \end{cases}$ $SE\{\log OR\} = \sqrt{\frac{1}{a}+\frac{1}{b}+\frac{1}{c}+\frac{1}{d}}$

Log odds ratio Test:

| ITT | PP: |
|---|---|
| $a=10,\ b=15.\ \ c=160\ \ d=165$ | $a=4\ \ b=8\ \ c=95\ \ d=110$ |
| $OR = \dfrac{10/160}{15/165} = 0.6875$ | $OR = \dfrac{4/95}{8/110} = 0.579$ |
| $\log OR = -0.3747$ | $\log OR = -0.5465$ |
| $SE\{\log OR\} = \sqrt{\frac{1}{10}+\frac{1}{15}+\frac{1}{160}+\frac{1}{165}} = 0.4231$ | $SE\{\log OR\} = \sqrt{\frac{1}{4}+\frac{1}{8}+\frac{1}{95}+\frac{1}{110}} = 0.6282$ |
| $Z = \dfrac{\log OR}{SE\{\log OR\}} = -0.8857 \approx -0.89$ | $Z = \dfrac{\log OR}{SE\{\log OR\}} = -0.8699 \approx -0.87$ |
| $Z_{1-\frac{\alpha}{2}} = Z_{0.975} = 1.96$ | $Z_{1-\frac{\alpha}{2}} = Z_{0.975} = 1.96$ |
| for $\lvert Z\rvert < Z_{0.975}$ | for $\lvert Z\rvert < Z_{0.975}$ |
| we conclude accept $H_0: \log(OR) = 0$ | we conclude accept $H_0\ \log OR = 0$ |

Confidence interval

Formula: $EF = \exp\{1.96 \times SE\{\log OR\}\}$ $CI = OR/EF \sim OR * EF$

| ITT: | PP: |
|---|---|
| $EF = \exp\{1.96 \times 0.4231\} = 2.29$ | $EF = \exp\{1.96 \times 0.6282\} = 3.4256$ |
| $CI = (\frac{0.6875}{2.29}\ \ \ 0.6875 \times 2.29)$ | $CI = (\frac{0.579}{3.4256}\ \ \ 0.579 * 3.4256)$ |
| $= (0.3\ \ \ 1.576)$ | $(0.169\ \ \ 1.9834)$ |