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HIV Vaccine study

Read the abstract for the Study “Placebo-controlled phase 3 trial of a recombinant glycoprotein 120 vaccine to prevent HIV-1 Infection” (at end of assignment, and handed out in class). This study investigated whether a vaccine could prevent the acquisition of HIV. There are 4 treatment groups

1) Men who received vaccine

2) Men who received placebo

3) Women who received vaccine,

4) Women who received placebo.

All individuals were HIV negative when the study began. They carried out 2 analyses: one for men, one for women. The main response variable is “infection” rate, which can be thought of for each individual as “infected or not infected”. For each person they also measured viral load, which is the number of viruses per red blood cell.

1) What type of statistical model would you use to analyze these data

**~~Paired t-test~~** **2-sample t-test** ANOVA regression chi-squared test

2) What kind of data is the response variable “infected or not infected”?

\_**qualitative**\_ I would give partial credit for this; more precise / conventional would be “categorical”; see key

2) What kind of data is the response variable “viral load”?

\_**quantitative**\_

3) What is the predictor?

\_**group that got the vaccine**\_

3) What kind of data is the predictor?

~~\_~~**~~quantitative~~**~~\_\_~~ categorical / factor it s a group; quantitative is used for something expressed as a number (eg, number of years using IV drugs)

4) What is the **statistical term** for the difference in viral load between **men who received the placebo** and men who received the vaccine.

**~~Comparison of two means~~ close to the right idea. This is the effect size. See key.**

5) The 95% confidence interval for the difference in viral load between **men who received the placebo** and men who received the vaccine contains zero. What does this indicate?

**~~That means that the experiment was significant~~ when the CI contains zero, it is *not* significant; p value will be > 0.05**

6) Did the authors do a good job reporting their results? Could they have done better?

**They did a good job because the results were straight forward and easy to interpret in particular they report means, sample sizes, confidence intervals**

7) What term could apply to the “**Exploratory … analyses”** they conducted?

**extra tests done comparing different variables; more or less the right idea; lots of test can lead to p-hacking**

8) Why do you think they “**adjusted for multiple … comparisons”** when they carried out their “Exploratory analyses”?

**There were more than two variables; close to the right idea – there were multiple statistical tests conducted**

9) What are two methods they could use to correct for multiple comparisons? (actually only one would work in this case, but those details aren’t important)

**Bonferonni, tukey**

10) This study had a large sample size (>5000 people). If the sample size was smaller (say 50), would the confidence intervals around the effect size get bigger or smaller (Assuming they got the same effect size as with the larger sample size).

**Confidence interval would be larger**

11) Imagine a different study where they gave anti-retroviral therapy to people who acquired HIV during this study. They compared each person’s viral load at the start of the study to their viral load a year later. What kind of statistical test would they use?

**Paired t-test** 2-sample t-test **~~ANOVA~~** regression chi-squared test

**This is a before-after scenario. Each person is paired with their future self.**

**Placebo-Controlled Phase 3 Trial of a Recombinant Glycoprotein 120 Vaccine to Prevent HIV-1 Infection**

[**https://academic.oup.com/jid/article/191/5/654/1234535/Placebo-Controlled-Phase-3-Trial-of-a-Recombinant**](https://academic.oup.com/jid/article/191/5/654/1234535/Placebo-Controlled-Phase-3-Trial-of-a-Recombinant)

The Journal of Infectious Diseases, Volume 191, Issue 5, 1 March 2005, Pages 654–665,

Abstract

Background

A **vaccine** is needed to prevent human immunodeficiency virus type 1 (**HIV**-1) infection

Methods

A double-blind, randomized trial of a recombinant HIV-1 envelope glycoprotein subunit (rgp120) **vaccine** was conducted among **men who have sex with men**[highest risk group] and **among women at high risk** for heterosexual transmission of HIV-1. Volunteers received 7 injections of either **vaccine or placebo** (ratio, 2:1) over 30 months. The primary end point was HIV-1 seroconversion over 36 months

Results

A total of 5403 volunteers (5095 men and 308 women) were evaluated. **The vaccine did not prevent HIV-1 acquisition**: infection rates were 6.7% in 3598 vaccinees and 7.0% in 1805 placebo recipients; vaccine efficacy (VE) was estimated as 6% (**95% confidence interval**, −17% to 24%). There were no significant differences in viral loads, rates of antiretroviral-therapy initiation, or the genetic characteristics of the infecting HIV-1 strains between treatment groups. **Exploratory … analyses** [extra analyses done using demographic data from the study, such as race, age, income] showed nonsignificant trends toward efficacy in preventing infection in the highest risk (VE, 43%; n=247) and nonwhite (VE, 47%; n=914) volunteers (P=.10, **adjusted for multiple … comparisons**)

**Conclusions**

**There was no overall protective effect.** The efficacy trends in subgroups may provide clues for the development of effective immunization approaches