



VCU

Virginia Commonwealth University
VCU Scholars Compass

VCU's Medical Journal Club: The Work of Future Health Professionals

2021

Double-Blind, Randomized, Placebo-Controlled Phase III Clinical Trial to Evaluate the Efficacy and Safety of treating Healthcare Professionals with the Adsorbed COVID-19 (Inactivated) Vaccine Manufactured by Sinovac: A structured summary of a study protocol for a randomised controlled trial

Valerie Lau

Follow this and additional works at: <https://scholarscompass.vcu.edu/mjc>



Part of the [Medicine and Health Sciences Commons](#)

© The Author(s)

Downloaded from

<https://scholarscompass.vcu.edu/mjc/9>

This Article Presentation is brought to you for free and open access by VCU Scholars Compass. It has been accepted for inclusion in VCU's Medical Journal Club: The Work of Future Health Professionals by an authorized administrator of VCU Scholars Compass. For more information, please contact libcompass@vcu.edu.

Double-Blind, Randomized, Placebo-Controlled Phase III Clinical Trial to Evaluate the Efficacy and Safety of treating Healthcare Professionals with the Adsorbed COVID-19 (Inactivated) Vaccine Manufactured by Sinovac :A structured summary of a study protocol for a randomised controlled trial

Authors: Ricardo Palacios, Elizabeth Gonzalez Patino, Roberta de Oliveria Piorelli, Monica Tilli Reis Pessoa Conde, Ana Paula Batista, Gang Zeng, Qianqian Xin, Esper G. Kallas, Jorge Flores, Christian F. Ockenhouse & Christopher Gast

Published: 15 October 2020

Valerie Lau

Context

Phase I

1. Vaccines are given to humans; small sample size (<100)
2. Given to healthy humans (ensure the efficacy of the vaccine)
3. Analyze side effects
4. Dosage: (Upper limit vs lower limit)

Phase II

1. Sample size increases (100-1000)
2. More representative sample group (age, gender, underlying diseases); not just healthy individuals
3. Monitoring side effects based on determined dosage

Phase III

1. Large sample size (13,060 participants)
2. Still matching demographics of population
3. Monitoring symptoms

Vocabulary Words

Randomized- Participants had an equal probability of being placed into control vs experimental group

Multicenter- Trials took place at multiple centers (Brazil)

Endpoint driven- At the end of the clinical trial, researchers can use the statistics to conclude whether the intervention technique was beneficial


Double blind- Neither the participants nor the experimenter are aware of which group the participants fall into (Control group vs. experimental group); minimize bias

Placebo controlled- One group is given a placebo vs the other receiving treatment

Adverse reaction- Any reactions that have a casual relationship to vaccination



Sinovac Vaccine

- Vaccines work by imitating an infection (usually involving inactivated viral components); helps acquire immunity; production of T-lymphocytes (destroy infected cells and make antibodies) and B-lymphocytes (target pathogens)
 - Sinovac Vaccine
 - Manufactured by Sinovac Life Sciences (Beijing, China)
 - Inactivated vaccine- genetic material of the pathogen is eliminated by heat, radiation, or chemicals; cannot replicate or cause illness
 - Immune response is not as strong as live attenuated vaccines (virus is weakened; can't cause major illness but can still replicate)
 - Less long lasting
 - Requires booster doses
- 

Design

Step 1

Qualifications

- 18 years or older, both genders, healthy/underlying diseases
- Health care professionals in close contact with COVID-19 patients
- Pregnant women, those breastfeeding, or plans to conceive within three months of receiving vaccine were excluded

Step 2

Assignments

- Randomized based on age (18-59 years and 60 years and older)
- Two randomization groups
 - 11,800 (18-59 year-old)
 - 1,260 elderly (above 60 year-old)

Step 2 Continued

Assignments (cont.)

- Half of the participants in each group were given the treatment and half were given the placebo
- Used a centralized randomization system for assignment

Design

Step 3

Experimentation

- Vaccine includes 3 ug/ 0.5 mL of the inactivated SARS-CoV-2 virus
- Adjuvant- aluminium hydroxide (helps boost the immune response)
 - Antigen remains for a longer period of time
- Placebo- aluminum hydroxide in 0.5 mL solution

Step 4

Schedule

- Vaccine and placebo (0.5mL doses) were given as IM injections (deltoid) in a two week interval

Step 5

Outcomes

- Assessment of efficacy based on WHO standards (protection level above 50%)
- Primary efficacy endpoint- incidence of symptomatic cases of COVID-19 two weeks after second injection (diagnosed clinically)
- Primary safety endpoint- any adverse reactions one week after vaccination in both groups

Discussion Questions

1. As the vaccine supply increases, do you think the people receiving the vaccine should be given a choice as to which one they want to receive?
2. What are your thoughts on the smaller sample size of senior citizens (1,260 participants above 60) compared to the other group (11,800 18-59 year-old). Should this Phase III trial have included more senior citizens because they are the most vulnerable group?
3. Moderna has started testing their vaccines on babies and young children, do you think that they should've started with the older children first? Since young children typically do not get severely ill.

Citations

1. Ricardo Palacios ORCID: orcid.org/0000-0002-1410-85791, Patiño1, E., Piorelli1, R., Conde1, M., Batista1, A., Zeng2, G., . . . Gast5, C. (2020, October 15). Double-Blind, randomized, Placebo-Controlled Phase III clinical trial to evaluate the efficacy and safety of treating healthcare professionals with the adsorbed COVID-19 (Inactivated) Vaccine manufactured by Sinovac – profiscov: A structured summary of a study protocol for a randomised controlled trial. Retrieved March 19, 2021, from <https://trialsjournal.biomedcentral.com/articles/10.1186/s13063-020-04775-4#availability-of-data-and-materials>
2. Vaccine types. (n.d.). Retrieved March 19, 2021, from <https://www.vaccines.gov/basics/types>
3. What's the difference between b-cells and t-cells? (2019, November 18). Retrieved March 19, 2021, from <https://www.cancercenter.com/community/blog/2017/05/whats-the-difference-b-cells-and-t-cells>