

Study Protocol

Comparative evaluation of the adverse effects of Vaccination against Covid 19 infection among the population in Central India.

Abstract:

Background: India's Covaxin and Covishield has associate effectiveness rate of 81% preliminary info. Both vaccines have shown excellent safety and efficacy.

Objectives: To seek the information about vaccination side effect and Covid-19 infection after getting vaccination.

Methodology: We are examining the self-reported vaccination side effect on local and systemic side-effects within 8 to 15 days and covid 19 infections who received one or two doses of the covishield or a covaxin.

Expected Results: The expected results of this study will determine the vaccination adverse-effects of covaxin and covishield with its probability of Covid-19 infection among the dental professionals after getting vaccination in state of Maharashtra.

Conclusion: An observational based study in which we have to identify vaccination side effects and infection after administration of both Coronavirus vaccines which are use in India. Both the vaccines area associate effectiveness rate of 81%.

Keywords: Vaccination, Covid 19 infection.

INTRODUCTION

The India's drug regulator gave disaster approval to coronavirus 2019 vaccines for using against corona virus disease even when 3rd phase clinical study for Covaxin is going on. On 3 January, the Indian general drugs controllers are approved the booster as a "heavy safeguard" in opposition the spread of the high contagious variant which is found in the Britain. India is the 2nd highest infected country in the world with more than 150,000 deaths due to coronavirus 2019 till December. Two vaccines are approved in India, first are Covishield and second are Covaxin. Both vaccines required 2 doses, after Four weeks they build up the immune response with a coronavirus spike protein. Covishield is an Indian sort which is prepared by the Serum Institute of India. It is universal's biggest vaccines mass producer¹. The manufacturer uses a weakened version of adenovirus. Phase III trials have started, with 1600 volunteer people in November. The 2 indigenously developed vaccine candidates 4 aged-group vaccination ways were observed: (1) Vaccines are given equally around the whole residents or were initially given to people who

was: (2) Young adults, (3) Middle adults, (4) Old adults². India's first manufactured vaccine is Covaxin which act against coronavirus disease 2019 which is prepared by Bharat Biotech in combine with the Indian Council of Medical Research and the National Institute of Virology. For trials, 25,800 volunteer people had signed. In Covaxin manufacture uses a deactivated coronavirus 2019 which is extracted from an asymptomatic patient coronavirus disease 2019 vaccine for older populations (60 year and above) decreases in death rate, no matter immunogen effectualness, management proceeding, rollout speed or immunity dynamics. Survey in general population is important when vaccination is rolling out. Country has supplied 6.4 Crores amount of booster to eighty-four nations³.

Rationale: This study will help to observe numbers of healthcare professionals are affected with vaccination side effect and covid infection after getting vaccination. We aimed to study safety and prospect of vaccination in Maharashtra.

Objectives:

- To evaluate the comparisons of adverse effects of vaccination against COVID 19 i.e. Covishield and Covaxin.
- To evaluate the co-relation of adverse effects of vaccination with age groups, gender, BMI, co-morbidities, Frequency of dose and covid infection post vaccination.

Methods:

Selection criteria:

Participants with Age group > 18 to 45 years, 45 years above, >45 years with co morbidities.

Measurement:

It is an online cross-sectional Survey conducted in Sharad pawar dental college and hospital among central India. The questions will be distributed to all dental healthcare professionals. Age group is distributed as > 18 to 45 years, 45 years above, >45 years with co morbidities. A questionnaire form is designed to record all relevant information. The questionnaire consisted a total 25 items to observe the adverse effects of vaccination against Covid 19 in India i.e. Covaxin and Covishield and recording the demographic details with Covid-19 infection post vaccination among the dental health professionals in state of Maharashtra.

Quantitative variables: All the demographic details and the questions in relation to the questionnaire will be recorded with the help of electronic forms and record in the excel sheet.

Statistical methods: Statistical software of SPSS version 22 has been used for the analysis. Descriptive analysis and frequency distribution test will be used to assess the responses of the participants towards the questionnaire.

Pearson co-relation and logistic regression analysis will be used for estimating the co-relation of adverse effects of vaccination with age groups, gender, BMI, co-morbidities, Frequency of dose and covid infection post vaccination.

Expected Outcomes/Results:

The expected results of this study will determine the vaccination adverse-effects of covaxin and covishield with its probability of coronavirus 2019 infection among dental professionals after getting vaccination in state of Maharashtra.

Discussion:

A prospective study was conducted in UK: Vaccine side effect and SARS-CoV2 infection after vaccination in users of covid symptoms study app. They aimed to investigate the safety and effectiveness of these vaccines in UK. They examined the quality and prospect of self-reported local and systemic side effects between 8 days of vaccination every single person is using covid symptoms study app. They also analyze the infection rates in subsets of vaccinated every single subsequent tested for coronavirus with PCR or lateral flow test with infection rates in unvaccinated controls. In phase 3 trials they conclude that local and systemic side effects after vaccination occur at lower frequency. After 12 days both the vaccines decrease the risk of coronavirus infection⁴.

A randomized control study was conducted in United States: adverse effect with coronavirus 2019 mRNA 1273 vaccine. The aim of study was to investigate the side effect of mRNA 1273 vaccine on healthcare workers. Through an independent online questioner serve they conclude that many of the symptoms reported are not hazardous. Of these, 58.8% were able to continue routine activity, 25% had temporary trouble to perform daily activities, 27.78% required short time off from work. 3.94% required outpatient provider, 0.23% required emergency help. Despite the broad arrangement of self-reported symptoms are shown to be a large number of receiving for this vaccine⁵. A number of studies have been reported on vaccination⁶⁻⁷ and Covid situation⁸⁻¹⁰. Bawiskar et. al. reported on haematological manifestations of covid-19 and emerging immunohaematological therapeutic strategies¹¹. Godhiwala et. al. reported about leukemoid reaction in a covid-19 patient¹². Khubchandani et. al. reported on Emerging Therapeutic Options for COVID-19¹³. Some interesting studies by Kute et. al.¹⁴, Nibudey et. al.¹⁵, Singh et. al.¹⁶ and Butola et. al.¹⁷ were reviewed.

Conclusion:

A community-based study in which we have to investigate assessment of adverse effects of Covid 19 Vaccination among dental health professionals in state of Maharashtra. Both the vaccines are associated effectiveness rate of 81%.

References:

1. Menni C, Klaser K, May A, Polidori L, Capdevila J, Louca P, Sudre CH, Nguyen LH, Drew DA, Merino J, Hu C. Vaccine side-effects and SARS-CoV-2 infection after vaccination in users of the COVID Symptom Study app in the UK: a prospective observational study. *The Lancet Infectious Diseases*. 2021 Apr 27.
2. Kadali RA, Janagama R, Peruru S, Gajula V, Madathala RR, Chennaiahgari N, Malayala SV. Adverse effects of COVID-19 mRNA-1273 vaccine: A randomized, cross-sectional study on healthcare workers with detailed self-reported symptoms. *Journal of Medical Virology*. 2021 Apr 6.

3. World Health Organization COVAX: Working for Global Equitable Access to COVID- 19 Vaccines(2020)
4. Prem K, Cook AR, Jit M. Projecting social contact matrices in 152 countries using contact surveys and demographic data. *PLoS computational biology*. 2017 Sep 12;13(9):e1005697.
5. Nandi A, Balasubramanian R, Laxminarayan R. Who is at the highest risk from COVID-19 in India? Analysis of health, healthcare access, and socioeconomic indicators at the district level. *medRxiv*. 2020 Jan 1.
6. Arriola, Carmen S., Piya Sutarattiwong, Fatimah S. Dawood, Giselle Soto, Prabir Das, Danielle R. Hunt, Chalinthorn Sinthuwattanawibool, et al. "What Do Pregnant Women Think about Influenza Disease and Vaccination Practices in Selected Countries." *HUMAN VACCINES & IMMUNOTHERAPEUTICS*, n.d. <https://doi.org/10.1080/21645515.2020.1851536>.
7. Vaidya, Harsha Dipak, and Premkumar P. Badwaik. "The Assessment of Parents' Awareness of Children Immunization as per Universal Immunization Program (UIP)." *INTERNATIONAL JOURNAL OF AYURVEDIC MEDICINE* 11, no. 4 (December 2020): 735–38.
8. Dhankasar, Priya, Pallavi Dhole, Seema Kolhe, Minal Dambare, Priya Rewatkar, and Vaishali Balpande. "The Unseen Positive Effect of Covid-19 Pandemic." *JOURNAL OF RESEARCH IN MEDICAL AND DENTAL SCIENCE* 8, no. 6 (2020): 108–12.
9. Acharya, Sourya, Samarth Shukla, and Neema Acharya. "Gospels of a Pandemic- A Metaphysical Commentary on the Current COVID-19 Crisis." *JOURNAL OF CLINICAL AND DIAGNOSTIC RESEARCH* 14, no. 6 (June 2020): OA01–2. <https://doi.org/10.7860/JCDR/2020/44627.13774>.
10. Arora, Devamsh, Muskan Sharma, Sourya Acharya, Samarth Shukla, and Neema Acharya. "India in 'Flattening the Curve' of COVID-19 Pandemic - Triumphs and Challenges Thereof." *JOURNAL OF EVOLUTION OF MEDICAL AND DENTAL SCIENCES-JEMDS* 9, no. 43 (October 26, 2020): 3252–55. <https://doi.org/10.14260/jemds/2020/713>.
11. Bawiskar, Nipun, Amol Andhale, Vidyashree Hulkoti, Sourya Acharya, and Samarth Shukla. "Haematological Manifestations of Covid-19 and Emerging Immunohaematological Therapeutic Strategies." *JOURNAL OF EVOLUTION OF MEDICAL AND DENTAL SCIENCES-JEMDS* 9, no. 46 (November 16, 2020): 3489–94. <https://doi.org/10.14260/jemds/2020/763>.
12. Godhiwala, Parth, Sourya Acharya, Gaurav Jagtap, Arvind Bhake, and Samarth Shukla. "Leukemoid Reaction in a COVID-19 Patient." *JOURNAL OF EVOLUTION OF MEDICAL AND DENTAL SCIENCES-JEMDS* 10, no. 6 (February 8, 2021): 399–400. <https://doi.org/10.14260/jemds/2021/88>.
13. Khubchandani, Sheetal Rameshlal, and Trupti Madhav Dahane. "Emerging Therapeutic Options for COVID-19." *JOURNAL OF EVOLUTION OF MEDICAL AND DENTAL SCIENCES-JEMDS* 9, no. 41 (October 12, 2020): 3082–85. <https://doi.org/10.14260/jemds/2020/677>.
14. Kute, Vivek, Sandeep Guleria, Jai Prakash, Sunil Shroff, Narayan Prasad, Sanjay K. Agarwal, Santosh Varughese, et al. "NOTTO Transplant Specific Guidelines with Reference to COVID-19." *INDIAN JOURNAL OF NEPHROLOGY* 30, no. 4 (August 2020): 215–20. https://doi.org/10.4103/ijn.IJN_299_20.

15. Nibudey, Akanksha Ram, Vidya SudhindraBaliga, and Prasad V. Dhadse. "To Keep COVID-19 Out of Hospitals in India - Are We Prepared?" JOURNAL OF EVOLUTION OF MEDICAL AND DENTAL SCIENCES-JEMDS 9, no. 37 (September 14, 2020): 2751–54. <https://doi.org/10.14260/jemds/2020/597>.
16. Singh, Kumar Tathagat, Gaurav Mishra, Alok Kumar Shukla, Subasish Behera, Arun Kumar Tiwari, SubhasishPanigrahi, and Kumar Gaurav Chhabra. "Preparedness among Dental Professionals towards COVID-19 in India." PAN AFRICAN MEDICAL JOURNAL 36 (June 19, 2020). <https://doi.org/10.11604/pamj.2020.36.108.23694>.
17. Butola, Lata Kanyal, Ranjit Ambad, Prakash KeshaoKute, Roshan Kumar Jha, and Amol Dattaroa Shinde. "The Pandemic of 21st Century - COVID-19." JOURNAL OF EVOLUTION OF MEDICAL AND DENTAL SCIENCES-JEMDS 9, no. 39 (September 28, 2020): 2913–18. <https://doi.org/10.14260/jemds/2020/637>.

UNDER PEER REVIEW