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COVAXIN- INDIA'S FIRST INDIGENOUS VACCINE - A REVIEW

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ABSTRACT

India stood top among countries worldwide that have been severely impacted by the COVID-19 pandemic. With a population of over 1.3 billion people, it was tough to keep the virus from spreading. Just months after recovering from the first wave, the second wave of infection erupted, causing the country's economy to suffer. Experience of facing the first and 2nd wave of covid-19 and the threat of Delta variant government decided that the only possible solution to fight against covid-19 is to vaccinate the people. COVAXIN created by Bharat Biotech in joined forces with the NIV (National Institute of Virology) of the ICMR (Indian Council of Medical Research) showed 78% efficiency against the COVID-19 virus and played a vital role in handling it. This review article aims to improve awareness among the people regarding COVAXIN along with the data supporting its performance.

Keywords: COVID-19; COVAXIN; efficacy; clinical trials

INTRODUCTION

The Covid-19 pandemic initially started as an epidemic in China and later encircled the world **[1]**. This Fortuitous disaster deteriorated both the global economy and human health. As per WHO Covid-19 dashboard until today [10/11/2021]

250,154,972 confirmed cases were reported along with 5,054,267deaths **[2]** in which 34,377,113 confirmed cases and 461,389 deaths are from India **[3]**. India is still under threat of Delta and 3rd wave, to prevent reoccurrence of cases Government of India increased vaccination in people. Until today [10/11/2021], India's overall COVID-19 Vaccination Coverage exceeds 1090 Million with a recovery rate of 98.25% **[4]**. COVAXIN is India's 1st native COVID-19 immunizing vaccine by an Indian company. COVAXIN is developed by Bharat Biotech in joined forces with the NIV (National Institute of Virology) of the ICMR (Indian Council of Medical Research). It's an inactivated vaccine prepared by using heat, chemicals, or radioactivity to inactivate or kill disease-carrying organisms **[5]**. Beyond 120 million shots of this vaccine were given to the Indian population [6].

MATERIALS AND METHODS

We gathered data from published workshops carried out on COVAXIN.

Dosage, quantity, and site of administration

COVAXIN requires two doses of administration. The dosage quantity per single dose is 0.5ml and administered through the intramuscular (IM) route **[7].**

Composition

Ingredients used in COVAXIN have Whole Virion, inactivated Coronavirus (SARS-CoV-2) antigen (Strain: NIV-2020-770), TLR7/8 Agonist (imidazoquinolinone), Aluminum Hydroxide Gel, 2-Phenoxyethanol, Phosphate Buffered Saline q.s. to 0.5 ml **[7].**

Dose schedules

The time gap between the first and second doses of COVAXIN is four to six weeks **[7]**.

Refrigerator temperatures

Unlike vaccines which require sub-zero degree storage temperature COVAXIN can be stored at 2-8°C which is suitable for many low to middle-income countries **[8]**.

Clinical trial results

Summary of COVAXIN Clinical trial data along with references given in **Table 1**.

AEFI (Adverse Events Following Immunization)

Side effects of COVAXIN include Injection site pain/ inflammation/ reddishness/ pruritus, pain in the head, pyrexia (fever), uneasiness/ body ache, Nausea, Vomiting, and Rashes **[7]**.

Precautions

The company specifies that the people who have the following conditions should not get COVAXIN. They are hypersensitivity, pyrexia (fever), hemophilia (bleeding disorder), or are on anticoagulants, immune

deficient or on medicine that affects your immune system, gestation, lactating, took different Carona vaccine, any other severe health-related concerns, as decided by the Vaccinator **[7]**.

Emergency use authorization

Emergency use authorization of COVAXIN data was given in **Table 2**.

Table 1: Summary of COVAXIN Clinical trial data

Clinical trial Phases	Summary	Reference
Phase I	Phase 1 study was performed on 375 subjects and estimated that the vaccine is safe and approved for the next phase.	[9]
Phase II	Phase 2 studies were performed on 380 individuals and showed significant immune response with mild to moderate adverse events with no severe adverse events.	[10]
Phase III	Phase 3 studies had conducted on 25,798 participants, and the results stated the vaccine efficiency as 78%.	[11]

Table 2: Emergency use authorization of COVAXIN

S. NO.	Emergency use authorization data	COVAXIN
1	Countries approved Emergency use authorization of COVAXIN.	COVAXIN has been permitted by India, Zimbabwe, Iran, the Philippines, Mexico, Nepal, Guyana, Paraguay, and Mauritius.
2	WHO (World Health Organization) approval	WHO has issued EUL (Emergency Use Listing) for COVAXIN on 3rd November 2021[12].
3	EMA approval	COVAXIN is yet to come under the rolling review process of EMA (European medicines agency).

VACCINE MIX

COVAXIN specifies that there is no scientific information on the suitability of taking COVAXIN with other vaccines **[7]**. Recently ICMR performed a study to estimate the Safety and Immunogenicity of vaccine mix in 18 (M/F: 11/7) individuals of Uttar Pradesh. The heterologous vaccine regime group (vaccine mix group) took COVISHIELD as the 1st dose and COVAXIN as the 2nd. The safety and immunogenicity responses of the heterologous vaccine regime group have been assessed with results generated by homologous prime-boost vaccination groups of COVISHIELD (M/F: 22/18) and COVAXIN (M/F: 17/23). Results declared that the heterologous vaccine group showed a higher immune response against Alpha, Beta, and Delta variants. The participant's IgG antibody and neutralising antibody responses were significantly higher in the heterologous group than in similar groups **[13]**.

Use of the vaccine in Pregnancy and Lactating women

COVAXIN stated that there is only limited information is available on the safety and efficiency of the vaccine in pregnant women

and specifies that they can't provide proper justification of risk based on this insufficient data. The vaccine should only be given to gestating women if the advantages of vaccination surpass the hazards. Ministry of Health & Family Welfare, Govt. of India said that a gestating women who chooses for vaccination could be vaccinated at any time of the pregnancy, and the information which is needed to study before making a decision have been provided in Operational Guidance for pregnant women published by MOHW (Ministry of Health and Family Welfare Government of India**) [14]**. WHO guidelines said that the vaccines may show similar efficacy in breastfeeding women as in normal individuals **[15]**, and COVAXIN approved by WHO is safer for them.

Vaccine effect on menstrual cycle

There is no data regarding the COVAXIN effect on menstrual cycle.

Vaccination of Pediatric population (aged <18 years old)

DCGI approved COVAXIN for emergency use in pediatric population between the age of 2 to 18 **[16]**.

CONCLUSION

COVAXIN showed an effective Immunogenicity to the COVID-19 virus with mild to moderate side effects. The vaccine displayed its capable of generating antibodies to fight against the Coronavirus and even if the person who was vaccinated got affected by the COVID-19 virus, they showed early recovery against the virus. The government of India provided awareness to citizens to get vaccinated to fight against the COVID-19 virus and that awareness triggered the vaccination rate in India.

Declarations

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Conflict of Interest

There is no conflict of interest.

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Nil

Ethics Statement

Not applicable

Informed Consent

Not applicable

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