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COVAXIN

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Abstract
Covaxin is India's indigenous vaccine developed by Bharat Biotech in collaboration with Indian Council Of Medical Research (ICMR). Clinical trials gives information regarding safety and immunogenicity of vaccine. Also covaxin having certain adverse effects which can be recovered within some days.Covaxinnot applicable for pregnant or lactating mothers. Temporary contraindication may involve person with active SARS CoV-2 infection.

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Covaxin was developed by Indian pharmaceutical company Bharat Biotech in collaboration with Indian Council Of Medical Research.Thehuman clinical trials of potential COVID-19 vaccine called Covaxin has started at AIIMS,NewDelhi.Thevaccine is similar to Corona Vac(tbe Chinese vaccine developed by Sinovac)in that it uses a complete infective SARS-COV-2 viral particles consisting of RNA surrounded by a protein shell, but modified so that it can't replicate.
The available data from phase 3 clinical trials suggest vaccine is safe and effective. Covaxin given in two dosage at the interval of 4 weeks in India's.
Vaccine helps in production of antibodies by antibody secreting cells and provide protective immunity .

Clinical trials:-
In phase I , antibody response elevated in those humans who received Covaxin. Immunogenicity and safety introduced in phase I clinical trial.
In phase llclinical trial arranged data indicate enhance immune response and tolerable safety outcomes.
Phase lll clinical trial was taken in November, 25,800 participants were involved in this phase. Bharat Biotech released interim efficacy data on 3 March 2021, which showed the clinical efficacy of 81%.

Table 1. Summary Results on SARS-CoV-2 Vaccine Trial Efficacy and Viral Neutralization of the B.1.1.7, P.1, and 501Y.V2 Variants, as Compared with Preexisting Variants.*

Vaccine (Company)	Preexisting Variants			Neutralization by Pseudovirion or Live Viral Plaque Assay			Efficacy in Settings with 501Y.V2 Variant
	Sample Size	Efficacy in Preventing Clinical Covid-19	Efficacy in Preventing Severe Covid-19	B.1.1.7 Variant	P.1 Variant	501Y.V2 Variant	
	no.	*% (no. of events with vaccine vs. placebo)*					%
Ad26.COV2.S (Johnson & Johnson)	43,783	66 (NA)	85 (NA)	NA	NA	NA	57†, 85‡
BNT162b2 (Pfizer)	34,922	95 (8 vs. 162)	90 (1 vs. 9)	Decrease by 2×	Decrease by 6.7×	Decrease by ≤6.5×	NA
mRNA-1273 (Moderna)	28,207	94 (11 vs. 185)	100 (0 vs. 30)	Decrease by 1.8×	Decrease by 4.5×	Decrease by ≤8.6×	NA
Sputnik V (Gamaleya)	19,866	92 (16 vs. 62)	100 (0 vs. 20)	NA	NA	NA	NA
AZD1222 (AstraZeneca)	17,177	67 (84 vs. 248)	100 (0 vs. 3)	NA	NA	Decrease by ≤86× to complete immune escape	22§
NVX-CoV2373 (Novavax)	15,000	89 (6 vs. 56)	100 (0 vs. 1)	Decrease by 1.8×	NA	NA	49§
CoronaVac (Sinovac)¶							
Brazil	12,396	51 (NA)	100 (NA)	NA	NA	NA	NA
Turkey	7,371	91 (3 vs. 26)	NA	NA	NA	NA	NA
BBIBP-CorV (Sinopharm)	NA	79 (NA)	NA	NA	NA	Decrease by 1.6×	NA

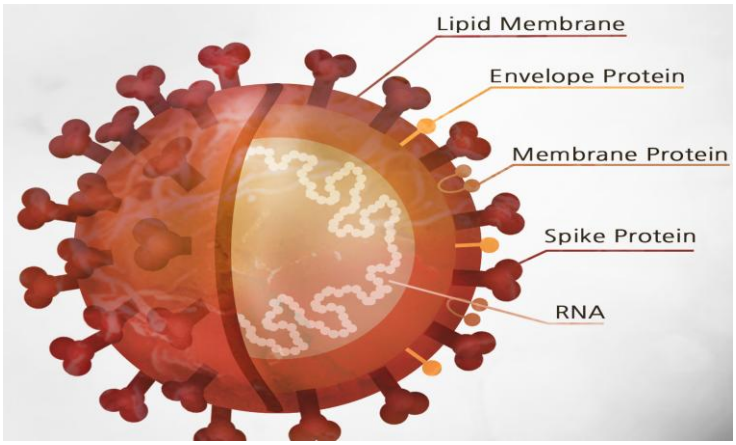
How does it work ?

Uses a form of the virus that has been inactivated or weakened so it doesn't cause disease,but still generates an immune response.

Uses a virus that has been genetically engineered so that it can't cause disease but produces coronavirus proteins to safety generates an immune response .

Spike protein

Uses a harmless fragments of proteins that mimic the COVID-19 virus to safety generates an immune respone. Synthetic DNA fragments (Plasmids) that encodes a COVID-19 antigenTypically the RNA segment of viral genome that codes for the virus spike protein (or other antigen region) is prepared in suspension of nanoparticles.



What else dose vaccine contain?

- Adjuvants
- Lipid nanoparticles (NLPs), present in vaccine only.
- Composition of Covaxin :-
- Inactivated Corona viruse
- Aluminum hydroxide gel
- TLR7/8agonist (Agonist:- A chemical substance that binds to receptor and activates the receptor to produce a biological response.)

- Phenoxyethanol
- Phosphate buffered saline

Post vaccination (second dose)SARS CoV-2 infection:-

From January 16 ,2021 (first day of vaccination) untill May 15,2021(21-36 days after second dose,data locking date),a total of 30 (30/492,6.1%) Health care workers (HCW) have reported to have COVID-19 among SARS CoV-2 native effectiveness(n=492) after the first dose of vaccination. From 30 participants 4 had suspected symptomatic and positive HRCTsigns but to RT-PCR or RAT) and 26 had confirmed (RT-PCR orRAT positive) COVID-19. Three SARS CoV-2 infection acquired before second dose,while 27 had acquired SARS CoV-2 infection after second dose. In covaxin recipients infections were noted in 2.2% (2/93)recipients. None of the cohort had COVID-19 following either vaccine had severe COVID requiring mechanical ventilation.

Median (interquartile range)anti-spike antibody titre after (day 21-36) the second dose of either vaccine.

CharacteristicsCovaxin
Antibody titer P
Median
(IQR)(inAU/mL)
Age
Age greater
than or equal to 6054.5(28.25-135). 0.285
36(8.5 – 127).
Sex
Male. 49(19.5-940.187
Female73(32-148).

Adverse effects of covaxin:-

- Injection site pain
- Swelling
- Fever
- Malaise
- Headache
- Nausea
- Vomiting
- Skin rashes

Who can take the COVID-19 vaccines?

All individuals above age 18 years are eligible to take except pregnant and lactating History of known allergies to injectiblevaccines or certain therapies, pharmaceutical products,food items are contraindicating conditions for COVID vaccine administration. But temporary contraindications may involve person with active SARS CoV-2 infection , those given anti SARS- CoV-2 monoclonal antibodies, and plasma and extremely unwell patients with other chronic ailments. Special precautions must be taken in those patients suffering from bleeding disorders, platelet disorders, clotting factor disorders and coagulopathies. There is no contraindication

For individuals with chronic morbities such as cardiac, neurological, pulmonary,metabolic,etc.., patient with a history of SARS-CoV-2 infection and HIV, immune suppression, the effect of COVID-19 vaccine in such cases may be slightly reduce.

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