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Covid-19: China's CoronaVac vaccine offers 83.5% protection against symptomatic infection, interim analysis finds

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Two doses of the new CoronaVac vaccine made in China have an efficacy of 83.5% against symptomatic covid-19, an interim analysis has shown.[1]

The vaccine, developed by the Chinese company Sinovac Life Sciences and made from inactivated SARS-CoV-2 virus, shows promise for global distribution because of its relative stability.

The phase III randomised controlled trial, conducted between September 2020 and January 2021 across 24 centres in Turkey, involved 10 218 participating adults between 18 and 59 years, randomly assigned to receive two doses of vaccine (6650) or placebo (3568). High risk healthcare workers as well as volunteers with an average covid-19 exposure risk in the community were recruited. Their average age was 45 years, and 58% were men.

The interim analysis, published in the *Lancet*, showed that during a median follow-up period of 43 days (interquartile range 36 to 48 days), nine cases of symptomatic covid-19, confirmed by polymerase chain reaction testing, were reported in the vaccine group (31.7 cases (14.6 to 59.3) per 1000 person-years) and 32 were reported in the placebo group (192.3 cases (135.7 to 261.1) per 1000 person-years) 14 days or more after the second dose, yielding a vaccine efficacy of 83.5% (95% confidence interval 65.4% to 92.1%; P<0.0001).

Lead author Murat Akova, from Hacettepe University Medical School in Turkey, said, "In order to bring the covid-19 pandemic under control, the world needs every single dose of safe and effective vaccines, and our results add important evidence of the safety and effectiveness of inactivated virus vaccines. One of the advantages of CoronaVac is that it does not need to be frozen, making it easier to transport and distribute. This could be particularly important for global distribution, as some countries may struggle to store large amounts of vaccine at very low temperatures."

Writing in a linked comment piece in the *Lancet*, Maheshi N Ramasamy and Lucy Jessop of the University of Oxford and the National Immunisation Office of the Health Service Executive, Ireland, respectively, said, "[The] findings suggest that two doses of CoronaVac have robust efficacy (within the WHO target product profile for SARS-CoV-2 vaccines) and acceptable tolerability when administered with a 14-day interval. CoronaVac is also available as single-dose vials, which improves ease of administration and reduces wastage."[2]

According to the report, analysis of the immune response in a subset of 1400 participants from both study groups showed that the vaccine induced a robust immune response in 90% (880 of 981), with the antibody response decreasing with older age in men and women.

The authors reported 1259 adverse events (18.9%) in the vaccine group and 603 (16.9%) in the placebo group (P=0.0108). Most (90%) were mild and included fatigue, injection site pain, and aching muscles, and there were no severe adverse events or deaths.

The authors acknowledged that because the analysis involved a short follow-up period and a relatively young and low risk population, and it took place before the emergence of variants of concern, further research was needed. Trial participants received doses 14 days apart, whereas vaccination in the community has involved a 28 day interval. The authors noted that, while it has been claimed that 28 day schemes lead to better immunogenicity, the longer the interval, the higher the chances of contracting covid-19 before becoming fully immunised.

Noting that the World Health Organization had given emergency use approval to another inactivated vaccine from a different Chinese producer (Sinopharm-Beijing), the authors added, "Our results add to the existing evidence on safety and efficacy of inactivated vaccines for prevention of covid-19."

The phase III trial results followed an earlier phase I and II trial that reported on the safety and immunogenicity of CoronaVac in healthy children and adolescents.[3]

1 Tanriover MD, Doğanay HL, Akova M, etal. Efficacy and safety of an inactivated whole-virion SARS-CoV-2 vaccine (CoronaVac): interim results of a double-blind, randomised, placebo-controlled, phase 3 trial in Turkey. *Lancet* 2021;(Jul). doi: 10.1016/S0140-6736(21)01429-X.

2 Ramasamy MN, Jessop LJ. CoronaVac: more data for regulators and policy makers. *Lancet* 2021;(Jul). doi: 10.1016/S0140-6736(21)01543-9.

3 Han B, Song Y, Li C, etal. Safety, tolerability, and immunogenicity of an inactivated SARS-CoV-2 vaccine (CoronaVac) in healthy children and adolescents: a double-blind, randomised, controlled, phase 1/2 clinical trial. *Lancet Infect Dis* 2021;(Jun):S1473-3099(21)00319-4. doi: 10.1016/S1473-3099(21)00319-4. pmid: 34197764