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Covid-19: Pfizer vaccine efficacy was 52% after first dose and 95% after second dose, paper shows

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The Pfizer and BioNTech covid-19 vaccine may provide some early protection, starting 12 days after the first dose, the peer reviewed results of a phase III trial have found.

The study, published in the *New England Journal of Medicine*,[1] found that vaccine efficacy between the first and second doses was 52% (95% credible interval 29.5% to 68.4%), with 39 cases of covid-19 in the vaccine group and 82 cases in the placebo group.

Seven or more days after the second dose, vaccine efficacy then rose to 95% (90.3% to 97.6%), with eight covid-19 cases reported in the vaccine group and 162 cases in the placebo group.

The vaccine has so far been approved in Canada and in the UK, where it is already being rolled out to people over 80 and healthcare workers. In the US the Food and Drug Administration's independent panel has voted in favour of emergency use authorisation for the vaccine, and the agency is expected to approve it within days.[2]

Participants

From July to November 2020, 43 448 adults were randomly assigned at 152 sites worldwide (including in Argentina, Brazil, Germany, South Africa, Turkey, and the US) as part of the phase II/III trial of the BNT162b2 vaccine. A total of 21 720 people received two doses 21 days apart, and 21 728 received a placebo.

The paper reported that, seven days after the second dose, vaccine efficacy ranged from 89% to 100% across subgroups defined by age, sex, race, ethnicity, baseline body mass index, and the presence of coexisting conditions.

The study found 10 severe covid-19 cases after the first dose, nine of which were in the placebo group. After the second dose it showed one case in the vaccine group and four in the placebo group.[3]

As of 9 October, 37 706 participants had a median of at least two months' safety data available after a second dose. Among these participants 49% were female, 83% were white, 9% were black or African-American, 28% were Hispanic or Latinx, 35% had a body mass index of at least 30, and 21% had at least one pre-existing condition. The median age was 52, and 42% of participants were aged over 55.

Adverse events

In terms of safety, more people in the covid-19 vaccine group reported any adverse event (27%, compared with 12% taking a placebo) or a related adverse event (21% *v* 5%). The researchers said that this was mainly due to transient reactogenicity events, such as injection site pain.

Few participants in either group had severe or serious adverse events. Among the BNT162b2 recipients four related serious adverse events were reported and two recipients died (one from arteriosclerosis and one from cardiac arrest), as did four placebo recipients (two from unknown causes, one from haemorrhagic stroke, and one from myocardial infarction). However, none of the deaths was considered by the investigators to be related to the vaccine or placebo, and no covid-19 associated deaths were observed.

The researchers wrote, "The safety profile of BNT162b2 was characterised by short term, mild-to-moderate pain at the injection site, fatigue, and headache. The incidence of serious adverse events was low and was similar in the vaccine and placebo groups."

1 Polack FP, Thomas SJ, Kitchin N, et al. Safety and efficacy of the BNT162b2 mRNA covid-19 vaccine. *N Engl J Med* 2020. doi: 10.1056/NEJMoa2034577. https://www.nejm.org/doi/full/10.1056/NEJMoa2034577?query=RP.

2 Tanne JH. Covid-19: FDA panel votes to approve Pfizer BioNTech vaccine. *BMJ* 2020;371:m4799doi: 10.1136/bmj.m4799.

3 Polack FP, Thomas SJ, Kitchin N, et al. Supplementary appendix to "Safety and efficacy of the BNT162b2 mRNA covid-19 vaccine." *N Engl J Med* 2020. https://www.nejm.org/doi/suppl/10.1056/NEJMoa2034577/suppl_file/nejmoa2034577_appendix.pdf.