

## RESEARCH SUMMARY

# Randomized Trial of BCG Vaccine to Protect against Covid-19 in Health Care Workers

Pittet LF et al. DOI: 10.1056/NEJMoa2212616

## CLINICAL PROBLEM

The bacille Calmette–Guérin (BCG) vaccine, used primarily against tuberculosis, has off-target immunomodulatory effects that might protect against other infections. Early in the SARS-CoV-2 pandemic, it was hypothesized that the BCG vaccine might enhance protection against Covid-19, but evidence of this effect is lacking.

## CLINICAL TRIAL

**Design:** A phase 3, multinational, double-blind, randomized, placebo-controlled trial evaluated whether the BCG-Denmark vaccine would reduce the incidence and severity of Covid-19 among health care workers.

**Intervention:** 3988 health care workers without a previous positive SARS-CoV-2 test were assigned to receive a single intradermal dose of BCG-Denmark vaccine (0.1 ml) or saline placebo. The two primary outcomes were symptomatic Covid-19 and severe Covid-19 during the 6 months after vaccination.

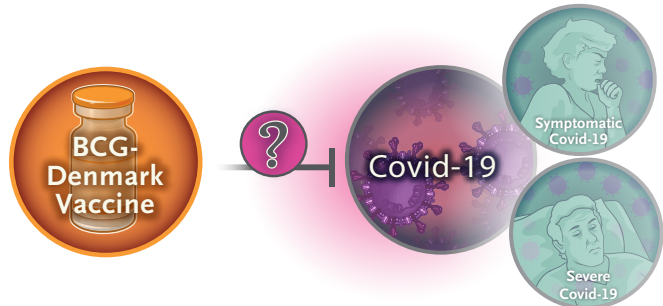
## RESULTS

**Efficacy:** Among 3386 participants who could be evaluated, the risk of symptomatic Covid-19 and severe Covid-19 did not differ significantly between the two groups.

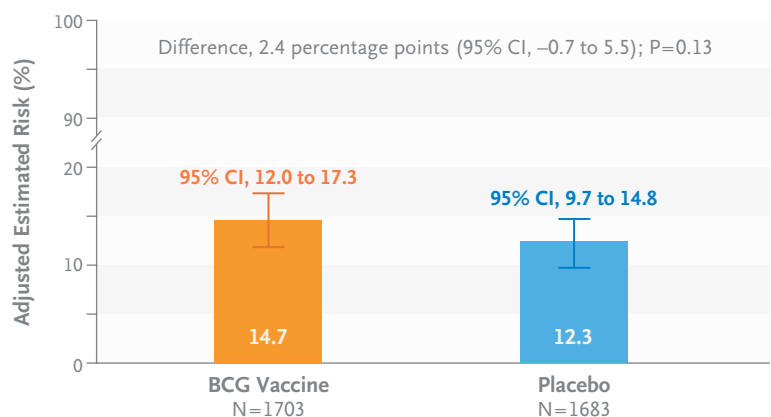
**Safety:** 20 participants in the vaccine group and 9 in the placebo group reported serious adverse events.

## LIMITATIONS

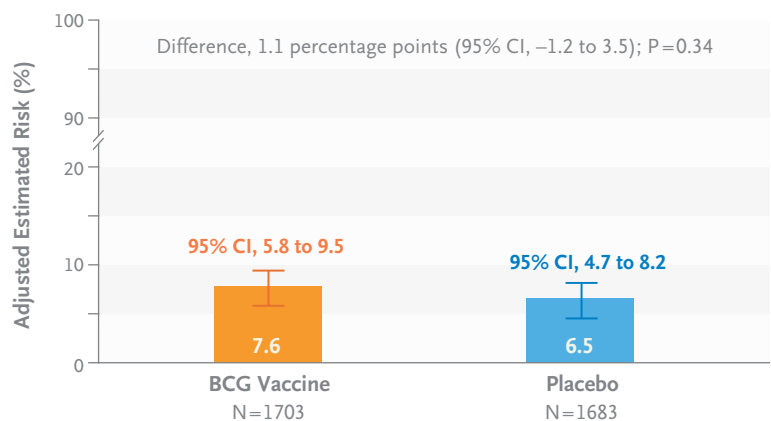
- The trial was underpowered, because recruitment was stopped early owing to the fact that Covid-19–specific vaccines became available.
- The trial definition of severe Covid-19 — which included being too sick to get out of bed or go to work for 3 consecutive days — differed from the definition more commonly used in studies (i.e., hospitalization or death).
- The definition of symptomatic Covid-19 did not include nonfebrile episodes without respiratory symptoms.



### Estimated Risk of Symptomatic Covid-19



### Estimated Risk of Severe Covid-19



## CONCLUSIONS

In health care workers without known previous SARS-CoV-2 infection, immunization with the BCG-Denmark vaccine did not result in a lower risk of symptomatic or severe Covid-19 than placebo.

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