BCG vaccination and COVID-19; follow-up advisory report

No. 2023/06, The Hague, March 29, 2023

Executive summary

Health Council of the Netherlands

Since late 2020, COVID-19 vaccines have been available that have proven effective in protecting against severe disease. At the start of the COVID-19 pandemic, when no COVID-19 vaccines were yet available, it was suggested that the tuberculosis vaccine (Bacillus Calmette-Guérin, BCG) could also have a protective effect against an infection with SARS-CoV-2. It is known that the BCG vaccine can be effective against infections other than tuberculosis, including respiratory infections (known as the 'non-specific effect'). On 5 October 2020, at the request of the Minister of Health, Welfare and Sport, the Health Council issued an advisory report on BCG vaccination and COVID-19.

At the time, there was insufficient data available to assess the efficacy and safety of BCG vaccination for COVID-19. More scientific data has since become available, and for this follow-up advisory report, the COVID-19 and BCG Vaccination Committee re-assessed whether BCG vaccination could be used against COVID-19, based on the current state of scientific

knowledge. In doing so, it applied the set framework used by the Health Council when assessing vaccinations.

Efficacy

The non-specific effects of BCG vaccination are ascribed to the innate immune system.

After vaccination with BCG, the innate immune system responds more strongly to an infection by an unrelated pathogenic micro-organism, at least temporarily. There is considerable variation in the degree to which the non-specific effects occur, ranging from a good response to no response at all.

Since the outbreak of COVID-19 a great deal of research has been conducted, with significant Dutch input, into the efficacy of BCG vaccination against COVID-19 in care providers, the elderly and adults with chronic conditions. This research includes randomised clinical studies in which participants were divided into an intervention group, which received a BCG vaccination, and a control group, which received no vaccination or

a placebo vaccination. Taking into consideration all the research now available, the Committee concludes that there is no compelling evidence for relevant effects of BCG vaccination or re-vaccination on the incidence of COVID-19 or absences due to COVID-19 among healthcare workers and the elderly (whether or not they have chronic conditions). There is also no compelling evidence for the efficacy of BCG vaccination or re-vaccination against severe disease from COVID-19.

Safety

Like all vaccines, BCG vaccination has adverse effects. These are mainly mild, local and transient in nature. For example, there may be pain or redness at the injection site. In one study involving elderly people with an underlying condition, an increase in the occurrence of coronary heart disease was seen in the group that received a BCG vaccine, compared with the group that received a placebo. Further analysis showed that a link between this finding and the

BCG vaccine was unlikely. Additional monitoring of the participants was considered desirable.

Recommendation

Based on the currently available scientific data, the Committee sees no reason to add BCG vaccination to the existing range of COVID-19 vaccinations.

The Health Council of the Netherlands, established in 1902, is an independent scientific advisory body. Its remit is "to advise the government and Parliament on the current level of knowledge with respect to public health issues and health (services) research..." (Section 22, Health Act).

The Health Council receives most requests for advice from the Ministers of Health, Welfare and Sport, Infrastructure and Water Management, Social Affairs and Employment, and Agriculture, Nature and Food Quality. The Council can publish advisory reports on its own initiative. It usually does this in order to ask attention for developments or trends that are thought to be relevant to government policy.

Most Health Council reports are prepared by multidisciplinary committees of Dutch or, sometimes, foreign experts, appointed in a personal capacity.

The reports are available to the public.

This publication can be downloaded from www.healthcouncil.nl.

Preferred citation:

Health Council of the Netherlands. BCG vaccination and COVID-19; follow-up advisory report.

The Hague: Health Council of the Netherlands, 2023; publication no. 2023/06.

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