

# BCG vaccination and COVID-19

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## Executive summary

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Health Council of the Netherlands



For the time being there is no vaccine against SARS-CoV-2, which is the virus that causes COVID-19. The vaccine against tuberculosis (Bacillus Calmette-Guérin, BCG) is known also to have an effect on infections other than tuberculosis, for example on respiratory tract infections (the so-called non-specific effect). If this vaccine were to have a protective effect in the context of a SARS-CoV-2 infection, the BCG vaccination could be used to bridge the period of time until we have a specific vaccine against SARS-CoV-2. For that reason the Minister of Health, Welfare and Sport (VWS) asked the Health Council of the Netherlands to clarify the scientific situation. The Committee COVID-19 and BCG vaccination has done so and based its work on the framework that the Council uses when assessing vaccinations.

### **Disease burden currently high, developments uncertain**

COVID-19 is a respiratory tract infection which can produce mild symptoms as well as very serious ones, leading to hospital admission and death. An outbreak in China has resulted in a pandemic. The Netherlands is experiencing a high disease burden with more than 76,000 confirmed hospital cases and over 6,200 confirmed deaths up until 8 September 2020. The actual figures are higher because not everyone has been tested. It is uncertain how the virus is going to continue spreading.

### **Efficacy and effectiveness unclear**

The non-specific effects of BCG vaccination can be attributed to the innate immune system which responds more robustly to infection after vaccination with BCG. Research among children indicates positive effects, but has not produced any convincing indications about the underlying

mechanisms. In the case of adults, even less data is available about the efficacy of BCG vaccination in the context of respiratory tract infections other than tuberculosis. The limited number of available studies seem to suggest that BCG vaccination could have a protective effect on respiratory tract infections in adults. However, the available data does not confirm the efficacy and effectiveness of BCG vaccination as possible protection against COVID-19.

### **Analysis of safety in the context of COVID-19 required**

The vaccination is regarded as safe for children and the committee does not generally see any reason to assume that this would be different in the case of healthy adults. However, a thorough analysis of the safety when used for COVID-19 is important because the effect of BCG vaccination is based on increased activity of the



innate immune system. That could constitute a risk because the most serious clinical pictures in the case of COVID-19 arise due to hypersensitivity of the immune system.

### **Cost-effectiveness and acceptability cannot be assessed**

Nothing is currently known about the cost-effectiveness of BCG vaccination in the context of COVID-19. Moreover, too little data is available to draw any conclusions about the usefulness and risk of this vaccination in the context of COVID-19. Future assessments of acceptability will be influenced by the fact that, in the Netherlands, the BCG vaccine is only registered as a vaccination against tuberculosis. What is more, large-scale use of BCG to combat COVID-19 may lead to a shortage of vaccine in countries where vaccination is essential in order to prevent tuberculosis in children.

### **New insights expected from current research**

Various studies have recently been started into the efficacy of BCG vaccination with regard to COVID-19. These studies usually involve medical staff and, to a lesser extent, elderly people and people with underlying conditions. The first results are expected to be available in 2021. The committee expects the studies to produce important insights.

### **Recommendation: reassessment as soon as the outcomes of the current trials are known**

For the time being too little data is available to assess whether the BCG vaccination could be used to combat COVID-19. The committee therefore recommends waiting for the outcomes of current trials. It will monitor the research and reassess the situation after sufficient scientific data has become available. The committee expects that other questions will also have to be answered. These relate to the effectiveness

outside of the research context, specific safety aspects relating to COVID-19, the efficacy among specific groups (such as vulnerable elderly people) and the efficacy duration. Additional research is therefore appropriate, some of which will have to be carried out, in the event of proven efficacy, by means of follow-up and monitoring after any introduction of the vaccination. Central management and coordination are also important at both national and international level (WHO, European Centre for Disease Prevention and Control). Other aspects which play a role in the future consideration of the use of BCG vaccination in the context of COVID-19 are the way in which the epidemiological situation progresses and the development of a specific vaccine against the virus.



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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.

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