

Rotavirus vaccination 2021

No. 2021/31, The Hague, June 30, 2021

Executive summary

Health Council of the Netherlands



Rotavirus is a pathogen that causes diarrhoea and vomiting. Young children are particularly susceptible to this intestinal infection (gastroenteritis) and can even end up in hospital with dehydration and organ failure. In the worst-case scenario, young children infected with the virus may die. There are two oral vaccines against this virus: Rotarix and Rotateq.

In 2017, the Health Council of the Netherlands recommended that the vaccination be given at least to children in high-risk groups, i.e. children born prematurely, children who were small for gestational age and children with a congenital defect. The Council also welcomed the inclusion of vaccination against rotavirus in the National Immunisation Programme, bearing in mind, however, that the cost-effectiveness of this vaccination was unfavourable when the asking prices of the vaccines were taken into account.

The government subsequently decided to start vaccinating children in high-risk groups from June 2020, although this was postponed due to the COVID-19 pandemic.

New studies conducted into the effectiveness of the vaccine in high-risk groups have since become available. This prompted the Ministry of Health, Welfare and Sport to once again ask the Health Council to publish an advisory report.

In preparing its advisory report, the Council's Vaccination Committee focused on the scientific evidence made available since the first opinion issued on rotavirus vaccination.

Disease burden

According to the Committee, the disease burden of rotavirus infections gives sufficient reason to consider vaccination. Severe symptoms can have a major impact on children and their families. Although the number of reported cases

of rotavirus and resulting hospital admissions was low in 2020, this was probably due to the lower risk of contamination because of the rules surrounding the coronavirus. The Committee expects that, after coronavirus measures are lifted, the number of rotavirus cases will return to the old level. From 2014 to 2019, an average of 3,600 children under the age of five were hospitalised with a rotavirus infection every year.

Efficacy and effectiveness

Recently published data show that universal vaccination against rotavirus, i.e. making all children eligible for a vaccine, is effective. Large-scale studies from the United States and Germany, for instance, show that the risk of severe diarrhoea and hospitalisation falls after launching a vaccination programme.

The effectiveness of only vaccinating high-risk groups is not as clear. The RIVAR study, a



Dutch prospective cohort study that followed over 700 at-risk children after receiving the rotavirus vaccine, was recently completed. In this study, rotavirus vaccination in this group did not reduce the number of cases of severe gastroenteritis or the hospitalisation rate.

As such, this study suggests that vaccinating children with risk factors is ineffective, although it should be noted that the results have not been published yet and that the study itself has various shortcomings. The study design, for instance, had its limitations and approximately one-third of all participants dropped out during the study. In addition, a US study that followed one of these risk groups did show that the rotavirus vaccine was effective, though slightly less effective than for children without any risk factors.

Rotavirus vaccination has several other positive effects, such as the fact that universal vaccination leads to herd immunity, the phenomenon that unvaccinated individuals in a vaccinated population may also be protected

against infection. Vaccination against rotavirus may also protect against the development of type 1 diabetes mellitus and coeliac disease, two conditions that have been indicated to be associated with rotavirus infection.

Safety

Recently published data confirm that rotavirus vaccination is sufficiently safe. Intussusception as a result of vaccination cannot be ruled out and may lead to intestinal obstruction, but the chance of this happening is extremely small. Moreover, intussusception is usually easy to treat. Other potential side effects are minor and usually do not require medical intervention. The RIVAR study shows that side effects also occur in vaccinated at-risk children, although these side effects rarely necessitated medical intervention. In terms of safety, the Committee sees no compelling reasons not to vaccinate children with or without risk factors.

Acceptability and efficiency

According to the Committee, universal vaccination against rotavirus is acceptable. It has come to this conclusion by considering and assessing all available information on the benefits and risks of vaccination. Despite the fact that the RIVAR study data show a less favourable benefit-risk ratio, the Committee stands by its the conclusion that vaccinating at-risk children against rotavirus is also acceptable.

According to the Committee, universal vaccination is not cost-effective at current vaccine price levels, based on the 2017 cost-effectiveness analysis. If vaccine prices fall, routine vaccination could become cost-effective.



Advice

As in its 2017 advisory report, the Committee welcomes offering universal vaccination against rotavirus through the National Immunisation Programme. Based on the RIVAR study, the Committee currently advises not to restrict rotavirus vaccination to children in the previously defined risk groups. It recommends that these children be included in the universal vaccination programme and that the results be monitored, as this can serve as a way to confirm or disprove the results of the RIVAR study.

The Committee has no clear preference for either vaccine, as both vaccines are comparable in terms of effectiveness and have similar safety profiles. The cost-effectiveness of universal vaccination against rotavirus is still unfavourable at current vaccine price levels.



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. Rotavirus vaccination 2021.

The Hague: Health Council of the Netherlands, 2021; publication no. 2021/31.

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