Health Council of the Netherlands

Immunisation against RSV in the first year of life

executive summary

Respiratory syncytial virus (RSV) is the most common cold virus in children. Most children only catch a cold from it, but in babies, RSV can lead to serious illness through bronchiolitis or pneumonia. Some groups of children, for example premature infants, children with Down syndrome or children with congenital heart defects are at increased risk of a more severe disease course. RSV infection can lead to hospitalisation; 1 to 2% of all children are admitted in their first year of life. The majority of hospitalised children were healthy prior to RSV infection.

Prior to the COVID-19 pandemic, RSV circulated in the Netherlands mainly in winter. During the COVID-19 pandemic in the winter of 2020/2021, RSV infections were rare, due to the measures taken to prevent transmission of SARS-CoV-2. However, the RSV epidemic returned in the summer of 2021: there was a peak in late July and the number of cases remained elevated for a year. In the winter of 2022/2023, the number of infections increased again from November and it is expected that the RSV season will again fall in autumn and winter in the future.

Currently, the antibody palivizumab is reimbursed for some medical risk groups. Palivizumab gives protection for 4 weeks after administration each time. Five shots are needed for protection during the entire RSV season, which lasts about 5 months. Recently, a new antibody nirsevimab has become available, which provides protection for at least 5 months. Unlike palivizumab, nirsevimab is registered for all newborns and infants, not just medical risk groups. With nirsevimab, one shot per RSV season is sufficient.

In addition to immunisation by administration of antibodies, children can also be protected by vaccination of the mother during pregnancy. The mother produces antibodies and passes them on to the foetus. A vaccine has recently been registered for maternal vaccination (Abrysvo®). That vaccine offers children protection against severe RSV infection up to about 6 months after birth.

Following the availability of the new antibody for children and of a vaccine for maternal vaccination, the State Secretary of Health, Welfare and Sport (VWS) asked the Health Council to advise on the desirability of using these agents for all children, through the National Vaccination Programme (RVP). The Health Council's Standing Committee on Vaccinations considered this question. The committee assessed immunisation with the

antibody nirsevimab and maternal vaccination separately, using the vaccination assessment framework.

Maternal vaccination is sufficiently effective in preventing (severe) RSV infection and hospitalisation in children up to 6 months old. It is then important to vaccinate the mother at least 2 weeks before delivery so that immunity can be transmitted from mother to child. Side effects are generally mild and short-lived. Further research is ongoing into a potential slightly increased risk of preterm birth. Nevertheless, according to the committee, the benefit of health gains for the children outweighs the drawbacks of side effects. This is true for women who give birth shortly before or during the RSV season. For women who give birth after the RSV season, maternal vaccination will be less useful. By the time the next RSV season starts again, the effectiveness of maternal vaccination for the child will have decreased.

The antibody nirsevimab has high efficacy against (very) severe RSV infections and hospitalisations. Immunisation with nirsevimab is safe; it causes few side effects. Children born just before or during the RSV season benefit most from nirsevimab if it is administered soon after birth (within 2 weeks at the latest). According to the committee, the health benefits of nirsevimab outweigh the disadvantage of the small risk of side effects.

According to the committee, for both means (immunisation with nirsevimab and maternal vaccination), the advantages outweigh the disadvantages. The committee has a preference for the use of immunisation with antibodies. There are three reasons for this:

- In immunisation with nirsevimab, seasonal timing of offering the antibodies allows a large proportion of children to be protected against RSV. With maternal vaccination, fewer children can be protected because a proportion are born out of season and efficacy has declined by the time they enter their first RSV season. These children could then be administered antibodies, but that means setting up two programmes. The committee prefers the use of one agent. More health gains could then be achieved with nirsevimab.
- Another advantage of immunisation with nirsevimab is that preterm infants can also be protected. With maternal vaccination, there is a chance that premature infants may be insufficiently protected against RSV after birth. If there are less than 2 weeks between vaccination and delivery, insufficient maternal antibodies have reached the foetus. These children may still be receiving nirsevimab, but the maternal vaccination will then have been in vain.
- Both agents offer newborns and infants good protection against RSV, but the safety of nirsevimab is more certain than the safety of maternal vaccination.

All in all, the committee recommends that protection against RSV be included in the RVP as soon as possible and that immunisation with nirsevimab be used for this purpose for all children. To minimise the risk of serious illness and hospitalisation of infants, children born just before or during the RSV season should be offered nirsevimab as soon as possible after birth (within 2 weeks at the latest). For children born after the RSV season, the committee recommends offering nirsevimab before the start of their first RSV season.

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