RSV Prevention in Infants and Young Children

Background

Respiratory syncytial (sin-SI-shul) virus, or RSV, is a common respiratory virus that may lead to only an upper respiratory infection but can also cause severe infections. It can be life-threatening, especially to infants and young children. Fortunately, severe infections can be prevented in most young infants by maternal vaccines and monoclonal antibodies.

This fact sheet will talk about two new options for prevention of severe RSV infection in infants:

1. **a maternal vaccine given to the mother during pregnancy that protects the infant after birth, and**
2. **infant immunization from antibodies to prevent severe RSV infections given to the infant after birth.**

For more information about RSV infections in infants and young children, go to www.thoracic.org/patients.





RSV Vaccines Given to Pregnant Women

What is the maternal RSV vaccine?

The maternal RSV vaccine (the currently available vaccine brand name is Abrysvo®) is a vaccine given to a pregnant woman and provides protection against RSV for their newborn baby. When a pregnant woman receives the RSV vaccine, their body activates their immune system and makes proteins or antibodies that protect against RSV. These antibodies are then passed along to their baby and protect the baby after birth.

When can the maternal RSV vaccine be given?

The maternal RSV vaccine can be given between 32 through 36 weeks of pregnancy during or just before the start of the RSV season. Depending on where you live, the RSV season may be different. In the United States, the RSV season is typically in the fall and winter. Ask your healthcare provider when the maternal RSV vaccine is available and recommended in your region.

How well does the maternal RSV vaccine work?

Studies show that the vaccine can reduce the risk of a infant being hospitalized from severe RSV infection by 57% and severe lower respiratory tract infection requiring medical care by 69%. Protection is strongest in the first 3 months of life.

How is the maternal RSV vaccine given?

The maternal RSV vaccine is given as a shot into the arm between 32 and 36 weeks of pregnancy.

*A meta-analysis is a where researchers gather all the good studies on the same question, then combine their results using statistics. The combined data gives a more reliable answer than any single study can.

What are possible side effects of the maternal RSV vaccine?

The most common side effects of the maternal RSV vaccine are pain at the site of the shot, headache, muscle pain, and nausea. As with any shot, there is a very small chance of a severe allergic reaction.

In clinical trials, it was reported that there was a small increase in the number of preterm births in those who received the maternal RSV vaccine, but it is not clear if this was related to the vaccine or other reasons unrelated to the vaccine. For this reason, the vaccine was approved for use only during 32 and 36 weeks of pregnancy, and the US Food and Drug Administration (FDA) is requiring continued monitoring of pregnant women receiving the vaccine.

Several post-marketing and real-world studies show that the maternal vaccine continues to be safe and effective at preventing severe infections and hospitalizations. Safety data are similar to the prelicensure studies. It is still not clear if there is a chance of increased preterm births because one study showed an increase while two other studies showed no increase (no association with the vaccine).

https://www.cdc.gov/mmwr/volumes/74/wr/mm7416a1.htm
https://pubmed.ncbi.nlm.nih.gov/38695784/
(meta-analysis of trials)*
https://pubmed.ncbi.nlm.nih.gov/40187782/
(possible preterm birth signal)
https://pubmed.ncbi.nlm.nih.gov/38976271/
(no association with preterm birth)
https://pubmed.ncbi.nlm.nih.gov/39969879/
(no association with preterm birth)

RSV Preventive Antibodies: RSV immunization given to infants and young children

What is a monoclonal antibody?

An antibody is a protein in the blood that targets antigens on viruses or other threats in the human body. Monoclonal antibodies are made to act like human antibodies and help the immune system fight off dangerous threats like viruses. Two long-acting monoclonal antibodies are approved for the prevention of severe RSV disease in infants: nirsevimab and clesrovimab.

What are nirsevimab and clesrovimab?

Nirsevimab (nir-SEV-i-mab, brand name Beyfortus®) and clesrovimab (cles-ro-VIH-zu-mab, brand name Enflonsia®) are monoclonal antibodies that prevent severe RSV disease. Nirsevimab is recommended for all infants, while clesrovimab is currently approved only for infants in their first season. Both nirsevimab and clesrovimab are long-acting, requiring only one dose that lasts for 5 months.

Who can receive nirsevimab and clesrovimab?

For infants whose mothers did not receive the maternal RSV vaccine, infants younger than 8 months of age during their first RSV season should receive nirsevimab or clesrovimab. In general, most infants born to mothers who received the RSV vaccine during pregnancy do not need either nirsevimab or clesrovimab. However, there are some exceptions, particularly for high-risk infants. These exceptions include infants born within 14 days of the mother's RSV vaccination, infants born to mothers with certain medical conditions or immunocompromised status, and infants undergoing procedures that may reduce the transfer of maternal antibodies.

In addition, children aged 8-19 months who are at high risk for severe RSV disease can also receive a dose of nirsevimab regardless of whether their mother received the RSV maternal vaccine in their first or second RSV season. High risk is defined as:

- Children born prematurely less than 32 weeks
- Chronic lung disease due to prematurity or another neonatal condition requiring medical support during the 6-month period before the start of the second RSV season.
- Children who are severely immunocompromised
- Children with cystic fibrosis with 1) severe lung disease and/or 2) poor growth with weight-for-length <10th percentile
- American Indian or Alaska Native children
- A lung abnormality or neuromuscular condition that places the child at high risk of severe RSV infection
- Trisomy 21 (Down Syndrome) or another chromosome abnormality that places the child at high risk of severe RSV infection.

When can your baby receive nirsevimab or clesrovimab?

Nirsevimab or clesrovimab can be given during or at the beginning of the RSV season. Depending on where you live, the RSV season may be different. In the United States, the RSV season is typically in the fall and winter. Ask your healthcare provider when nirsevimab or clesrovimab are available and recommended in your region.

How well do nirsevimab and clesrovimab work?

Nirsevimab and clesrovimab are highly are highly effective (works well) and reduce the risk of severe RSV disease by about 80%. Nirsevimab and clesrovimab last for 5 months, which is how long a typical RSV season lasts. Nirsevimab and clesrovimab protect infants when they are at highest risk of getting very sick from RSV. The RSV monoclonal antibodies do not work against other viruses. Babies can still get other colds or viral infections.

How are nirsevimab and clesrovimab given?

Nirsevimab and clesrovimab are given as a shot, usually in the baby's thigh muscle. Only 1 dose is needed during an RSV season.

What are possible side effects of nirsevimab and clesrovimab?

The most common side effects are pain, redness, swelling at the site of the shot, and rash. As with any shot, there is a very small chance of a severe allergic reaction, but this has not been seen in the clinical trials.

Several post-marketing and real-world studies, including meta-analyses (which look at results across multiple studies), have shown that nirsevimab is safe and effective at preventing severe infections and hospitalizations. Safety data are similar to those reported in the prelicensure studies. As clesrovimab was recently approved there are currently no post-marketing studies

https://pubmed.ncbi.nlm.nih.gov/39652359/

https://pubmed.ncbi.nlm.nih.gov/39773919/

https://pubmed.ncbi.nlm.nih.gov/40319903/ (meta-analysis)

How to decide between maternal vaccine and preventive antibodies?

It is good that we have several ways to help protect your newborn baby from severe RSV infection. Some doctors' offices do not carry RSV preventive antibodies. It may be harder to get in some areas, so it is important to discuss with your healthcare provider which option is best for you and your baby and how you can get it.

Maternal RSV Vaccine Benefits

- The newborn baby is immediately protected right after birth (if maternal RSV vaccine was given at least 14 days before birth)
- Fewer shots for the baby after birth

RSV Preventive Antibody Benefits

- The infant is protected once they receive the monoclonal antibody.
- There were no safety concerns in the immunization trials

Authors: Ferdinand Cacho, MD; Marianna Sockrider, MD, DrPH

Reviewer: Tina Hartert, MD, MPH

Summary Points

- **There are multiple options to prevent serious RSV infection in your baby:**

  1) maternal RSV vaccine given to a mother during pregnancy and

  2) RSV antibody prevention product given directly to the baby.

- **The maternal RSV vaccine works by activating the mother's immune system. The mother's antibodies are then passed onto the baby during pregnancy so that the baby is born with protection against severe RSV infection.**
- **The RSV antibody prevention products (nirsevimab and clesrovimab) work by giving the baby antibodies directly that protect against severe RSV infection.**
- **Ask your healthcare provider which option is best for you and your baby.**

Additional Resources:

American Thoracic Society
https://site.thoracic.org/advocacy-patients/patient-resources

- RSV in adults
- RSV Prevention
- How vaccines work

Centers for Disease Control (CDC):
https://www.cdc.gov/rsv/about/prevention.html

American Academy of Pediatrics (AAP):
aap.org/en/patient-care/respiratory-syncytial-virus-rsv-prevention/rsv-frequently-asked-questions/

healthychildren.org/English/health-issues/conditions/chest-lungs/Pages/RSV-When-Its-More-Than-Just-a-Cold.aspx

Nemours:
https://kidshealth.org/en/parents/rsv.html

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