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Passive Immunisation of Infants against RSV Infections (respiratory syncytial viruses)

RSV Prophylaxis with Monoclonal Antibody (nirsevimab, Beyfortus®) in Newborns

Patientenname und -adresse

Hello,

The purpose of this informed consent leaflet is to help you prepare for the patient-doctor discussion. Please read it carefully before the discussion and complete the questionnaire carefully and in full.

What is RSV?

RSV is an RNA virus which is widespread throughout the world. RSV infections are the most frequent cause of diseases in the lower respiratory tract of infants and small children. Just like influenza, RSV diseases tend to be seasonal and occur more frequently in autumn and winter. There is no effective treatment of the cause; only the symptoms can be alleviated. Infants and small children can become especially ill with RSV the first time they are infected. Within the first year of life, 50–70 % of children have suffered at least one RSV infection, and almost all children by the end of their second year. There is no long-lasting immunity. RSV infections are the most common reason for infants and small children to be admitted for inpatient treatment.

The initial infection is associated with disease symptoms such as a runny nose, dry cough, fatigue and fever. If the lower respiratory tract is also affected, the smallest branches of the bronchial tubes become inflamed. This is associated with respiratory problems such as wheezing during exhalation and respiratory distress. The trachea and bronchial tubes may also become inflamed at the same time, or pneumonia may occur. Acute inflammation of the middle ear is also possible.

It is possible to prevent infection by way of passive immunisation with “monoclonal antibodies”. This passive immunisation is recommended by the Standing Committee on Vaccination (STIKO) as of July 2024 in order to protect infants from the often severe course of the RSV diseases. There is currently no classic vaccine (active immunisation) available for infants.

Who should be immunised?

The STIKO recommends RSV prophylaxis with nirsevimab (Beyfortus®) for all newborn babies and infants in order to prevent serious RSV-related disease in their first RSV season. Where possible, infants who were born between April and September should receive the immunisation in the autumn before the start of their first RSV season, in the period between September and November. Newborns who were born during the RSV season (mainly between October and March) should receive nirsevimab as promptly as possible after birth, ideally upon discharge from the birth centre or at the second medical examination (3 to 10 days old). A missed nirsevimab dose should be caught up on as quickly as possible within the first RSV season.

Immunisation

Antibodies (immunoglobulins) are protective substances which are produced by specific immune cells in the body, e.g. if there is a viral or bacterial infection or also after an active immunisation (vaccination). These antibodies then offer protection from (further) infections. Antibodies can also be administered from outside; known examples are passive immunisation against tetanus, measles, rabies or hepatitis B in case of a possible infection.

In the case of conventional vaccines, the immune system of the recipient is stimulated to produce antibodies by components of antigens (active immunisation). With this immunisation (with nirsevimab), a pre-engineered antibody is administered which offers direct, immediate protection against RSV (passive immunisation). The antibody can neutralise the viruses if an infant has become infected, and thus highly likely prevent a severe course of disease.

Nirsevimab is injected once into the side of the thigh muscle. Two different dosages are available as a single dose: newborn babies or infants with a body weight less than 5 kg receive 50 mg and children with a body weight of 5 kg and above receive 100 mg.

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In order to prevent RSV diseases in children with a high risk of severe RSV illness (infants with bronchopulmonary dysplasia or haemodynamic heart defects), nirsevimab can be used as an alternative to Synagis (palivizumab) during the second RSV season. In this case, the single dose is 200 mg. This is administered by way of two 100 mg doses.

The aim of immunisation is to reduce severe courses of RSV disease of the lower respiratory tract in newborn babies and infants during their first RSV season, and to prevent RSV-related hospital admissions, treatment in intensive care and RSV-related deaths.

Nirsevimab can be administered at the same time as the standard childhood vaccinations or at any time.

Are any alternative methods available?

A further option for preventing RSV diseases in newborn babies and infants is to vaccinate the mother during pregnancy, which leads to a transmission of the antibodies to the child (maternal passive immunity). A vaccine was approved in the EU in 2023. However, the STIKO does not yet recommend the vaccination (at August 2024) as there is too little data available.

Who should not be treated?

Infants who have already suffered an RSV infection confirmed by laboratory testing, should generally not be immunised. Caution is advised with children who have a low platelet count or other coagulation disorders.

The antibody should not be used on infants and small children who have a history of severe hypersensitivity reactions to nirsevimab. Just as with other routine childhood vaccinations, mild infections are no valid reason not to immunise.

Risks and potential complications

Nirsevimab is generally well tolerated.

- After administration of nirsevimab (Beyfortus®), the child may experience brief **local reactions such as pain, redness and swelling at the injection site or a rash**. The infants and small children may also develop a **fever**. These reactions usually resolve within a few days.
- After administration of monoclonal antibodies, **severe hypersensitivity reactions** (allergic reactions) may occur in very rare cases, or even anaphylactic shock in isolated cases. This has not been reported before now for the nirsevimab preparation, but occurrence in isolated cases cannot be ruled out.

Since the immunisation is still new, no long-term experience is available. This means that unknown side-effects may occur.

During the patient-doctor discussion, you should ask all questions that are important to you or about anything that is still unclear!

Questionnaire (patient history)

By answering the questions carefully, you will help identify possible risks. **For patient's guardians, caregivers, legal representatives:** Please answer all questions from the child's viewpoint.

Personal information

1. Date of birth: _____
2. Height (in cm): _____
3. Weight (in kg): _____
4. Gender:
   - ☐ female
   - ☐ male
   - ☐ diverse
   - ☐ not specified

Important questions

n = no/y = yes

1. Is there an allergy?
   - ☐ no
   - ☐ medications
   - ☐ anaesthetic agents
   - ☐ contrast medium
   - ☐ latex
   - ☐ disinfectants
   - ☐ iodine
   - ☐ plaster
   - ☐ synthetic materials
   - ☐ and/or: _____
2. Is there a disorder of blood coagulation?
   - ☐ no
   - ☐ haemophilia
   - ☐ thrombocytopenia
   - ☐ von Willebrand-Jürgens disease
   - ☐ factor deficiency
   - ☐ and/or: _____
3. Is there a coagulation disorder among blood relatives? ☐ n ☐ y
4. Are there any other diseases? ☐ n ☐ y

   If yes, please indicate: _____

Doctor's comments

I have informed the patient's guardian about the procedure using the informed consent leaflet at hand, discussing in particular the following aspects and individual unusual circumstances (e.g. individual risk profile; underlying diseases; alternative treatment methods; medications; additional treatment measures; chances of success; instructions; after-care; special urgency or demands on the body; duration of the discussion; determination of the patient's ability to comprehend; minors; patient has a legal surrogate decision-maker/a legal guardian; patient has appointed a legal representative/provided a medical power of attorney; information provided in response to the questions, etc.):

_____

_____

_____

_____

_____

_____

_____

_____

_____

Proposed date for the vaccination: _____
Date

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Only in case of refusal to consent

I was informed about the planned measure. I do **not** consent to its implementation. I was emphatically informed that my refusal might result in significant health consequences.

Place, date, time

Patient's guardian*

Witness (if applicable)

Doctor

Statement of Consent

I have read the informed consent leaflet, and I understand it. The above-named measure, its nature and significance, alternatives, the risks and possible associated complications, chances of success, possible necessary changes, extensions as well as additional/subsequent procedures have been fully explained to me in a patient-doctor discussion with

doctor _____.

My questions have been answered completely and clearly.

I have **no further questions**, feel that **the counselling was satisfactory**, **do not need any further time for consideration** and **consent** to the proposed measure and any medically necessary, including unforeseeable, changes, extensions, additional and subsequent procedures.

I will follow the doctor's **instructions**.

I have received a duplicate/copy of this leaflet.

Place, date, time

Patient's guardian*

Doctor

* Only if the patient is a minor: If only one of the patient's guardians signs, with this signature, they confirm that they have sole custody of the child or that they are acting in agreement with the other of the patient's guardians. As a rule, both of the patient's guardians should sign for major procedures. Minor patients who are able to comprehend should also always sign.

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