



# ESTIMATED RATE OF THERAPEUTIC FAILURE WITH PALIVIZUMAB IN THE PROPHYLAXIS OF RESPIRATORY SYNCYTIAL VIRUS

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## Background

There is doubt about the criteria for selection of patients eligible to receive palivizumab prophylaxis for respiratory syncytial virus (RSV) and the potential therapeutic failures.

## Purpose

To estimate the rate of therapeutic failure with palivizumab and drug use profile in the study centre.

## Material and methods

Observational, retrospective study. Patients who received palivizumab in 3 seasons (2006-2009) were selected and medical records were reviewed.

Variables:

- ✓ Dependent: Rate of therapeutic failure with palivizumab.
- ✓ Independent: Profile of drug use in the study centre.

## Results

Data were obtained from 104 patients:

- 15/104 were children <2 years with hemodynamically significant congenital heart disease
- 10/104 children <2 years with bronchopulmonary dysplasia (BPD)
- 65/104 patients were preterm born before the 35th week of gestation
- 14/104 patients did not fit the approved indications

In 100% of patients, palivizumab was prescribed according to the recommended dosage, and the adequacy of the number of prescribed doses was 99%.

81.7% of patients received all prescribed doses.

Other risk factors analysed:

- ✓ 66/104 were male.
- ✓ 13/104 had a chronological age <10 weeks at the start of the season and 9/104 were born in the first 10 weeks of the season.
- ✓ 40/99 had low birth weight (1500-2500g), 45/99 very low birth weight (<1500g), 14/99 the right birth weight, 5/104 unknown birth weight.
- ✓ Breastfeeding was continued for at least 2 months in 42/93 patients.

The rate of therapeutic failure with palivizumab was 3.8%, of the total 104 patients receiving prophylaxis with palivizumab, 4 required hospitalization for RSV infection.

## Conclusions

- ✓ The drug use profile in the study centre matched the licensed indications in the SmPC. A protocol that allows an annual review of the criteria for selecting patients for treatment with palivizumab was developed.
- ✓ The rate of therapeutic failure in our study context was very low, so the drug can be considered effective.