Effect of palivizumab on respiratory syncytial virus-associated burden of disease – a randomized controlled trial.

No registrations found.

Ethical review	Not applicable
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23199

Source
NTR

Brief title
N/A

Health condition

1. Respiratory syncytial virus bronchiolitis;

2. infant wheeze;

3. post-bronchiolitis wheeze.

Intervention

Outcome measures

Primary outcome

1. Number of wheezing days during the first year of life.

Secondary outcome

1. Health-related quality of life at age 1,3 and 6 years;

2. Asthmatic symptoms at age 3 and 6 years measured by questionnaires.

Study description

Background summary

Respiratory syncytial virus (RSV) lower respiratory tract infection (LRTI) is the most frequent cause of bronchiolitis during infancy. During the winter season RSV bronchiolitis is one the most common causes of hospitalization. About 10% of hospitalized children with RSV LRTI require mechanical ventilation. Long-term airway morbidity occurs in about half of hospitalized infants with RSV LRTI, which is referred to as post-bronchiolitis wheeze (PBW). Good evidence exists that milder forms of RSV LRTI, which do not require hospital admission, are also associated with post-bronchiolitis wheeze. It has been shown that post-bronchiolitis wheeze is associated with decreased health-related quality of life over a broad range of domains.

Two non-excluding alternative hypotheses have been mentioned in the pathogenesis of RSV infection and post-bronchiolitis wheeze. First, it is possible that pre-existent pathology underlies both RSV infection and post-bronchiolitis wheeze (parallel hypothesis). It has been suggested that congenital decreased lung function precedes RSV infection. However, this still requires formal proof.

Prevention of severe RSV infection in preterm infants with gestational age <36 weeks is possible using monthly infection with palivizumab during the winter season. This effect of this humanized monoclonal antibody has been established in a large randomized controlled trial. In the Netherlands this drug is only used up to gestational age 32 weeks. Preterm children with gestational age 32-35 weeks are not prophylactically treated with palivizumab because of high costs.

It is not known whether recurrent wheeze in preterm children is caused by RSV infection (serial hypothesis) or that RSV infection is the first indication of chronic airway morbidity that would develop anyway (parallel hypothesis). This study aims to distinguish between these two hypotheses by investigating whether prevention of RSV (by palivizumab) results in decreased incidence of recurrent wheeze.

In this randomized controlled trial the number of wheezing days in the first year of life will be compared between infants receiving palivizumab and placebo. Definite results are expected in 2011.

Study objective

Prevention of respiratory syncytial virus infection using palivizumab in preterm children with gestational age 32-35 weeks will result in decreased incidence of recurrent episodes of wheeze (post-bronchiolitis wheeze).

Study design

N/A

Intervention

Monthly injection of placebo or palivizumab 15 mg/kg during the winter season.

Contacts

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Eligibility criteria

Inclusion criteria

1. Gestational age 32-35 weeks.

Exclusion criteria

1. Severe congenital anomaly;

2. Congenital heart disease;

3. Down syndrome.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2007
Enrollment:	452
Type:	Actual

Ethics review

Not applicable

Application type: Not applicable

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL994
NTR-old	NTR1023
Other	:
ISRCTN	incomplete

Study results

Summary results
N/A