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

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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).

Ethische beoordeling	Niet van toepassing
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23199

Bron
Nationaal Trial Register

Verkorte titel
N/A

Aandoening

1. Respiratory syncytial virus bronchiolitis;

2. infant wheeze;

3. post-bronchiolitis wheeze.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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).

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Gestational age 32-35 weeks.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Severe congenital anomaly;

2. Congenital heart disease;

3. Down syndrome.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-10-2007
Aantal proefpersonen:	452
Type:	Werkelijke startdatum

Ethische beoordeling

Niet van toepassing
Soort: Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL994
NTR-old	NTR1023
Ander register	:
ISRCTN	incomplete

Resultaten

Samenvatting resultaten
N/A