

Prevention of Respiratory Infections and Management among Children (PRIMAKid).

Gepubliceerd: 05-09-2005 Laatste bijgewerkt: 18-08-2022

Combined pneumococcal vaccination with influenza vaccination reduces the occurrence of RTI in children with recurrent RTI.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27299

Bron

Nationaal Trial Register

Verkorte titel

PRIMAKid

Aandoening

recurrent upper and lower respiratory tract infections (RTI).

Ondersteuning

Primaire sponsor: The Netherlands Organization for Health Research and Development ZONMW (grant number 2200.0121)

Overige ondersteuning: The Netherlands Organization for Health Research and Development ZONMW (grant number 2200.0121)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Number of febrile RTI-episodes.

Toelichting onderzoek

Achtergrond van het onderzoek

The PRIMAKid trial is a general practice based double-blind randomized placebo-controlled trial on the effectiveness and costs of combined influenza and pneumococcal vaccination in pre-school children with recurrent respiratory tract infections. A target number of 660 children aged 18-72 months with a history of two or more general practitioner attended episodes of RTI, are included.

Exclusion criteria are diseases accompanied by a high risk of recurrent RTI and conditions chronically treated with corticosteroids. Over a period of 7 to 22 months follow-up, the number of febrile RTI-episodes as primary outcome is assessed, and as secondary outcomes the severity and length of febrile RTI-episodes, medical visits / interventions, health-related quality of life and productivity loss of parents.

Doel van het onderzoek

Combined pneumococcal vaccination with influenza vaccination reduces the occurrence of RTI in children with recurrent RTI.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Study intervention 1:

combined heptavalent pneumococcal conjugate vaccine twice and trivalent inactivated influenza vaccine (IV) twice with one repeated IV after 1 year. (5 doses in total).

2.:

combined IV twice and placebo vaccine (saline fluid) twice) with a repeated IV after 1 year.

3.:

Control intervention: combined Hepatitis B vaccine twice and placebo vaccine (saline fluid) twice with one repeated Hepatitis B vaccination after 1 year.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age between 18-72 months;
2. A history of two or more episodes of general practitioner attended RTIs.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. No intention to move within 12 months to another region;
2. Provision of informed consent;
3. Good mastering of the Dutch language;

4. Absence of chronic diseases such as asthma treated with corticosteroids or high-risk disease (such as palatoschisis, Down syndrome, cystic fibrosis, etc.);
5. No previous influenza vaccination or pneumococcal vaccination or Hepatitis B vaccination;
6. No hypersensitivity to eggs and/or antibiotics, and/or serious history of serious adverse events through vaccination.

Onderzoeksopzet

Opzet

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

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	01-09-2003
Aantal proefpersonen:	660
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies	
Datum:	05-09-2005
Soort:	Eerste indiening

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	NL186
NTR-old	NTR223
Ander register	: N/A
ISRCTN	ISRCTN84713819

Resultaten

Samenvatting resultaten

Schonbeck Y, Sanders EA, Hoes AW, Schilder AG, Verheij TJ, Hak E.

Rationale and design of the prevention of respiratory infections and management in children (PRIMAKid) study: a randomized controlled trial on the effectiveness and costs of combined influenza and pneumococcal vaccination in pre-school children with recurrent respiratory tract infections.

Vaccine. 2005 Sep 30;23(41):4906-14