

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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27299

Source

Nationaal Trial Register

Brief title

PRIMAKid

Health condition

recurrent upper and lower respiratory tract infections (RTI).

Sponsors and support

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

Source(s) of monetary or material Support: The Netherlands Organization for Health Research and Development ZONMW (grant number 2200.0121)

Intervention

Outcome measures

Primary outcome

Number of febrile RTI-episodes.

Secondary outcome

Severity and length of febrile RTI-episodes as well as RTI-associated antibiotic prescriptions, medical visits, clinical laboratory diagnostic procedures, specialist referral and treatment with procedures like ventilatory tube placement or adeno-tonsillectomy, improvement of health-related quality of life, and reduced productivity loss of parents. Follow-up time varies from 7 to 22 months.

Study description

Background summary

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.

Study objective

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

Study design

N/A

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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.

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):	01-09-2003
Enrollment:	660
Type:	Actual

Ethics review

Positive opinion	
Date:	05-09-2005
Application type:	First submission

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	NL186
NTR-old	NTR223
Other	: N/A
ISRCTN	ISRCTN84713819

Study results

Summary results

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