

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

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON27299

### Source

NTR

### 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.

<br>

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.<br>

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