# Prevention of Respiratory Infections and MAnagement among Children

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
20/12/2005	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
20/12/2005	Completed	Results
Last Edited	Condition category	Individual participant data
15/05/2009	Respiratory	Record updated in last year

#### Plain English summary of protocol

Not provided at time of registration

## Contact information

#### Type(s)

Scientific

#### Contact name

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## Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

Secondary identifying numbers

**NTR223** 

## Study information

#### Scientific Title

Effectiveness and costs of combined influenza and pneumococcal vaccination in pre-school children with recurrent respiratory tract infections (RTI): a general practice-based randomised controlled trial

#### **Acronym**

**PRIMAKId** 

#### Study objectives

Combined pneumococcal vaccination with influenza vaccination reduces the occurrence of respiratory tract infections (RTI) in children with recurrent RTI.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Received from the local medical ethics committee

#### Study design

Randomised double blind placebo-controlled parallel group trial

#### Primary study design

Interventional

#### Secondary study design

Randomised controlled trial

#### Study setting(s)

Hospital

#### Study type(s)

**Treatment** 

#### Participant information sheet

#### Health condition(s) or problem(s) studied

Respiratory tract infection (RTI)

#### **Interventions**

- 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

#### Intervention Type

Other

#### **Phase**

Not Applicable

#### Primary outcome measure

Number of febrile RTI episodes

#### Secondary outcome measures

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.

#### Overall study start date

01/09/2003

#### Completion date

30/06/2005

# **Eligibility**

#### Key inclusion criteria

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

#### Participant type(s)

Patient

#### Age group

Child

#### Lower age limit

18 Months

#### Upper age limit

72 Months

#### Sex

Both

#### Target number of participants

660

#### Key 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

#### Date of first enrolment

01/09/2003

#### Date of final enrolment

30/06/2005

## Locations

#### Countries of recruitment

Netherlands

# Study participating centre University Medical Center Utrecht Utrecht

Netherlands 3508 GA

# Sponsor information

#### Organisation

The Netherlands Organisation for Health Research and Development (ZonMw) (Netherlands)

### Sponsor details

P.O. Box 93245 Den Haag Netherlands 2509 AE +31 (0)70 349 5111 info@zonmw.nl

#### Sponsor type

Research organisation

#### Website

http://www.zonmw.nl

#### **ROR**

https://ror.org/01yaj9a77

# Funder(s)

#### Funder type

Research organisation

#### Funder Name

The Netherlands Organisation for Health Research and Development (ZonMw) (Netherlands)

## **Results and Publications**

## Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration