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# Prevention of Respiratory Infections and MAnagement among Children

| Submission date | Recruitment status | [ ] Prospectively registered |
|---|---|---|
| 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

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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
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# Sponsor information

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

**Sponsor details**
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**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