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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

Protocol serial number
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

Primary study design
Interventional

Study design
Randomised double blind placebo-controlled parallel group trial

Study type(s)
Treatment

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(s)
Number of febrile RTI episodes

Key secondary outcome(s)
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.

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

Healthy volunteers allowed
No

Age group
Child

Lower age limit
18 Months

Upper age limit
72 Months

Sex
All

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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration