

Prevention of Respiratory Infections and Management among Children

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr A.G.S.C. Jansen

Contact details
University Medical Center Utrecht
Julius Center for Health Sciences and Primary Care
P.O. Box 85500
Utrecht
Netherlands
3508 GA
+31 (0)30 253 8640
A.G.S.C.Jansen@umcutrecht.nl

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

Study design

Randomised double blind placebo-controlled parallel group trial

Primary study design

Interventional

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