

Local anti-inflammatory treatment in the prevention of long-term airway morbidity following hospitalisation for respiratory syncytial virus (RSV) infection: clinical effectiveness and immunological correlates

Submission date 02/09/2005	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 14/09/2005	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 03/09/2014	Condition category Respiratory	☐ Individual participant data

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
3.2.03.22

Study information

Scientific Title

Local anti-inflammatory treatment in the prevention of long-term airway morbidity following hospitalisation for respiratory syncytial virus (RSV) infection: clinical effectiveness and immunological correlates - a randomised controlled trial

Study objectives

Inhaled corticosteroids during the first three months following admission for respiratory syncytial virus (RSV) lower respiratory tract infection (LRTI) prevent the occurrence and severity of long-term airway morbidity.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Review Committee of University Medical Center Utrecht, 17/05/2005, ref: 04-056

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Respiratory syncytial virus lower respiratory tract infection (RSV LRTI)

Interventions

1. Intervention starts within 24 hours following positive immunofluorescence for RSV infection
2. Hydrofluoroalkane (HFA)-based beclomethasone dipropionate (Qvar, 3M) or placebo
3. 200 µg twice daily during three months

Subgroup-analyses

1. Analyses of children with wheezing during primary infection versus those not wheezing
2. Analyses of children with a qualitative good inhalation technique versus those without a good technique
3. Analyses of children with different pharmacogenetic polymorphisms (NR3C1: rs6191; NR3C1: SNPNR3C1; JUN: rs11688; FOS: rs7101; NFKB2: rs7897947; VDR: rs10735810; VDR: rs1544410; VDR: rs731236; IL13: rs20541; IL13: rs1800925; CRHR1: rs242941) (this information was added to this record as of the 12th June 2007)
4. Analyses of children with mechanical ventilation versus those without mechanical ventilation

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Corticosteroids

Primary outcome(s)

Wheezing according to log registration from 3 until 15 months after hospitalisation for RSV LRTI

Key secondary outcome(s)

1. Wheezing according to log registration from hospitalisation until 15 months after hospitalisation
2. Coughing during follow up
3. Use of inhaled steroids (other than the intervention medication)
4. Use of bronchodilators
5. Days of hospitalisation
6. Respiratory Distress Assessment Instrument (RDAI) scores during hospitalisation
7. Local cytokine profiles (nasal aspirates) during the first three episodes of respiratory tract infections
8. Quality of life
9. Lung function (interrupter resistance measurement, RINT)
10. Physician-diagnosed asthma at the age of 6 years

Completion date

01/10/2013

Eligibility**Key inclusion criteria**

1. Infants under 13 months of age
2. Hospital admission for RSV LRTI
3. Positive immunofluorescence for RSV infection of epithelial cells in nasopharyngeal aspirates

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Upper age limit

13 Months

Sex

All

Key exclusion criteria

1. Previous use of steroids
2. History of cardiac or pulmonary disease
3. Wheezing illness prior to RSV LRTI

Date of first enrolment

01/10/2004

Date of final enrolment

01/10/2013

Locations

Countries of recruitment

Netherlands

Study participating centre

Department of Pediatrics

Utrecht

Netherlands

3508 AB

Sponsor information

Organisation

Dutch Asthma Foundation (Netherlands)

ROR

<https://ror.org/00ddgbf74>

Funder(s)

Funder type

Charity

Funder Name

Dutch Asthma Foundation (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	31/03/2009		Yes	No
Results article	results	01/01/2014		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes