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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

Registration date
14/09/2005

Overall study status
Completed

Last Edited
03/09/2014

Condition category
Respiratory

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.rsv.umcutrecht.nl

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Secondary outcome measures
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

Overall study start date
01/10/2004

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

Age group
Child

Upper age limit
13 Months

Sex
Both

Target number of participants
250

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)

Sponsor details
Speelkamp 28
P.O. Box 5
Leusden
Netherlands
3830 AA

Sponsor type
Charity

Website
http://www.astmafonds.nl

ROR
https://ror.org/00ddgbf74

Funder(s)

Funder type
Charity

Funder Name
Dutch Asthma Foundation (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

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