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Dutch Antibiotics in Respiratory syncytial virus infection Trial

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	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
07/01/2021	Respiratory	

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
N/A

Study information

Scientific Title
Dutch Antibiotics in Respiratory syncytial virus infection Trial

Acronym
DART

Study objectives
Antibiotic treatment of hospitalised children with Respiratory Syncytial Virus Lower Respiratory Tract Disease (RSV LRTD) has no beneficial effect on the clinical course.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Randomised, placebo controlled, parallel group, double blinded multicentre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Respiratory tract infection, Bronchiolitis, Pneumonia, Respiratory Syncytial Virus (RSV)

Interventions
Azithromycine 10 mg/kg/day for three days versus placebo.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Azithromycine

Primary outcome measure
Duration of hospitalisation

Secondary outcome measures
1. Proportion and duration of oxygen therapy
2. Proportion and duration of bronchodilator therapy
3. Duration of tachypnoe (more than 40 breaths/min)
4. Duration of fever (more than 37.5°C)
5. Duration of impaired feeding
6. Number of infants referred to Paediatric Intensive Care Unit (PICU)
7. Course of RSV score

Overall study start date
01/10/2001

Completion date
01/04/2006

Eligibility

Key inclusion criteria
Children less than 24 months of age with a virologically confirmed diagnosis of RSV LRTD, defined by a first episode of dyspnoea with increased body temperature (more than 37.5°C), and /or cough, coryza, wheezing, crackles on pulmonary auscultation.

Participant type(s)
Patient

Age group
Child

Upper age limit
24 Months

Sex
Not Specified

Target number of participants
120

Total final enrolment
71

Key exclusion criteria
1. Age more than 24 months
2. Children presenting with apnoea with signs of lower respiratory tract disease
3. Nosocomial RSV infection
4. Antibiotic treatment less than seven days before hospital admission
5. Absence of informed consent by parents or legal representatives

Date of first enrolment
01/10/2001

Date of final enrolment
01/04/2006

Locations

Countries of recruitment
Netherlands

Study participating centre
VU University Medical Centre
Amsterdam
Netherlands
1007 MB

Sponsor information

Organisation
VU University Medical Centre (The Netherlands)

Sponsor details
Department of Pediatrics
P.O. Box 7057
Amsterdam
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1007 MB

Sponsor type
University/education

Website
http://www.vumc.nl/english/

ROR
https://ror.org/00q6h8f30

Funder(s)

Funder type
Not defined

Funder Name
Not provided at time of registration

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	01/02/2008	07/01/2021	Yes	No