

Dutch Antibiotics in RSV infection Trial.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22490

Source

NTR

Brief title

DART

Health condition

RSV lower respiratory tract disease (bronchiolitis or pneumonia).

Sponsors and support

Primary sponsor: VU university medical center

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Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

Duration of hospitalisation.

Secondary outcome

1. Proportion and duration of oxygen therapy;
2. Proportion and duration of bronchodilator therapy;
3. Duration of tachypnoe (>40 breaths/min);
4. Duration of fever (> 37.5°C);
5. Duration of impaired feeding;
6. Number of infants referred to PICU
Course of RSV score.

Study description

Background summary

N/A

Study objective

Antibiotic treatment of hospitalised children with RSV LRTD has no beneficial effect on the clinical course.

Study design

N/A

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

Children <24 months of age with a virologically confirmed diagnosis of RSV lower respiratory tract disease, defined by a first episode of dyspnoea with increased body temperature (> 37.5° C), and/or cough, and/or coryza, and/or wheezing, and/or crackles on pulmonary auscultation.

Exclusion criteria

Age >24 months, children presenting with apnoea with signs of lower respiratory tract disease, nosocomial RSV infection, antibiotic treatment less than 7 days before hospital admission, absence of informed consent by parents or legal representatives.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2001
Enrollment:	120
Type:	Actual

Ethics review

Positive opinion	
Date:	24-08-2005
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL111
NTR-old	NTR142
Other	: N/A
ISRCTN	ISRCTN86554663

Study results

Summary results

Pediatr Pulmonol. 2008 Feb;43(2):142-9.