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The effect of macrolide antibiotics on the outcome of acute bronchiolitis in infants

Submission date 12/09/2003	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 12/09/2003	**Overall study status** Completed	
Last Edited 05/02/2018	**Condition category** 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
N0544103921

Study information

Scientific Title
The effect of macrolide antibiotics on the outcome of acute bronchiolitis in infants

Study objectives
The effect of macrolide antibiotics on the outcome of acute bronchiolitis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

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 to request a patient information sheet

Health condition(s) or problem(s) studied
Respiratory: Acute bronchiolitis

Interventions
The project involves enrolment of infants with bronchiolitis (a wheezy respiratory illness). Subjects will be randomised to receive either 5 days of clarithromycin suspension or placebo in double-blinded fashion.

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome measure
Outcome measures will include a daily clinical score and number of days hospitalisation

Secondary outcome measures
Not provided at time of registration

Overall study start date
16/10/2001

Completion date
15/10/2004

Eligibility

Key inclusion criteria
Not provided at time of registration

Participant type(s)
Patient

Age group
Child

Sex
Both

Target number of participants
Not provided at time of registration

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
16/10/2001

Date of final enrolment
15/10/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Addenbrooke's NHS Trust
Cambridge

United Kingdom
CB2 2QQ

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Other

Funder Name
Cambridge Consortium - Addenbrooke's (UK)

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