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Treatment of wheezy infants with bronchodilators (comparison of inhaled ipratropium bromide versus inhaled salbutamol)

Submission date 12/09/2003	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 12/09/2003	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 11/10/2016	**Condition category** Signs and Symptoms	[_] Individual participant data [_] Record updated in last year

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

N0051096269

Study information

Scientific Title
Treatment of wheezy infants with bronchodilators (comparison of inhaled ipratropium bromide versus inhaled salbutamol)

Study objectives
Infants with significant recurrent or persistent wheeze, who have a tendency towards atopy, will improve with inhaled ipratropium bromide.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised double-blind controlled cross-over 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 contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Wheezing

Interventions
Comparison of inhaled ipratropium bromide versus inhaled salbutamol.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)

Ipratropium bromide, salbutamol

Primary outcome measure
Efficacy

Secondary outcome measures
Not provided at time of registration

Overall study start date
26/04/2001

Completion date
01/06/2003

Eligibility

Key inclusion criteria
Children aged 3 to 18 months with persistent or recurrent wheezing and atopic tendencies

Participant type(s)
Patient

Age group
Child

Lower age limit
3 Months

Upper age limit
18 Months

Sex
Both

Target number of participants
Not provided at time of registration

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
26/04/2001

Date of final enrolment
01/06/2003

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Brighton & Sussex University Hospitals NHS Trust (RA)
Brighton
United Kingdom
BN1 3JN

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
Government

Funder Name
Brighton and Sussex University Hospitals NHS Trust (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