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N of 1 trials of Montelukast (ML) or Singulair™ in childhood asthma

Submission date	Recruitment status	[ ] Prospectively registered
12/09/2003	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
12/09/2003	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
30/04/2015	Respiratory	[ ] 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

Protocol serial number
N0256111271

Study information

Scientific Title
N of 1 trials of Montelukast (ML) or Singulair™ in childhood asthma

Study objectives
Does Montelukast improve asthma in n of 1 placebo trials in paediatric patients whose asthma is controlled by inhaled steroid?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Respiratory: Asthma

Interventions
Montelukast vs placebo

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome(s)
Service outcomes development

Key secondary outcome(s)
Not provided at time of registration

Completion date
09/09/2004

Eligibility

Key inclusion criteria
30 patients, 12 patients recruited 2001-2002

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Sex
All

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
09/09/2001

Date of final enrolment
09/09/2004

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Royal Free Hampstead NHS Trust
London
United Kingdom
NW3 2QG

Sponsor information

Organisation
Department of Health (UK)

Funder(s)

Funder type
Government

Funder Name
The Royal Free Hampstead NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration