

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

Submission date	Recruitment status	<input type="checkbox"/> Prospectively registered
12/09/2003	No longer recruiting	<input type="checkbox"/> Protocol
Registration date	Overall study status	<input type="checkbox"/> Statistical analysis plan
12/09/2003	Completed	<input type="checkbox"/> Results
Last Edited	Condition category	<input type="checkbox"/> Individual participant data
30/04/2015	Respiratory	<input type="checkbox"/> 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

Study design

Randomised controlled trial

Primary study design

Interventional

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