

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

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

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 measure

Service outcomes development

Secondary outcome measures

Not provided at time of registration

Overall study start date

09/09/2001

Completion date

09/09/2004

Eligibility

Key inclusion criteria

30 patients, 12 patients recruited 2001-2002

Participant type(s)

Patient

Age group

Child

Sex

Both

Target number of participants

30

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

England

United Kingdom

Study participating centre

Royal Free Hampstead NHS Trust

London

United Kingdom

NW3 2QG

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

The Royal Free Hampstead 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