

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

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 30/04/2015	Condition category Respiratory	☐ 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

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