

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

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