# Add-on salmeterol versus montelukast in Arg /Arg-16 asthmatics

Submission date	Recruitment status No longer recruiting Overall study status Completed	Prospectively registered	
		Protocol Statistical analysis plan	
31/07/2008		[X] Results	
Last Edited 09/11/2012	<b>Condition category</b> Respiratory	[] Individual participant data	

## Plain English summary of protocol

Not provided at time of registration

# **Contact information**

**Type(s)** Scientific

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### **Contact details**

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# Additional identifiers

EudraCT/CTIS number

#### **IRAS number**

ClinicalTrials.gov number NCT00655616

Secondary identifying numbers sm2006msd01

# Study information

#### Scientific Title

A proof-of-concept study to evaluate the benefit from add-on therapy with montelukast versus salmeterol in children with asthma carrying the Arg/Arg-16 beta2-receptor genotype

#### **Study objectives**

The purpose of this study is to determine whether patients with asthma who carry a genotype associated with adverse outcomes with long-acting beta-2 agonists like salmeterol show greater benefit from the use of an asthma drug that works via alternative pathways like montelukast.

**Ethics approval required** Old ethics approval format

#### Ethics approval(s)

Ethics approval received from Tayside Committee on Medical Research Ethics on the 2nd November 2006 (ref: 06/S1401/86).

**Study design** Interventional, single-centre, randomised controlled trial

**Primary study design** Interventional

**Secondary study design** Randomised controlled trial

**Study setting(s)** Hospital

Study type(s)

Treatment

#### Participant information sheet

Not available in web format, please use the contact details provided in the interventions field to request a patient information sheet

## Health condition(s) or problem(s) studied

Asthma

#### Interventions

Group one (comparison):

1. Seretide 100 Accuhaler (50 micrograms of salmeterol and 100 micrograms of fluticasone propionate) 1 dose twice daily plus 1 tablet daily of placebo montelukast

2. Seretide 250 Accuhaler (50 micrograms of salmeterol and 250 micrograms of fluticasone propionate) 1 dose twice daily plus 1 tablet daily of placebo montelukast

3. Seretide 500 Accuhaler (50 micrograms of salmeterol and 500 micrograms of fluticasone propionate) 1 dose twice daily plus 1 tablet daily of placebo montelukast

Group two (active):

 Flixotide Accuhaler (fluticasone propionate) 50 micrograms per blister; 1 blister dose twice daily plus 1 tablet daily of montelukast
Flixotide Accuhaler (fluticasone propionate) 100 micrograms per blister; 1 blister dose twice daily plus 1 tablet daily of montelukast
Flixotide Accuhaler (fluticasone propionate) 250 micrograms per blister; 1 blister dose twice daily plus 1 tablet daily of montelukast
Flixotide Accuhaler (fluticasone propionate) 250 micrograms per blister; 1 blister dose twice daily plus 1 tablet daily of montelukast
Flixotide Accuhaler (fluticasone propionate) 500 micrograms per blister; 1 blister dose twice daily plus 1 tablet daily of montelukast

Doses of montelukast or placebo: Up to 6 years: 4 mg once daily 6 - 14 years: 5 mg once daily 15 years and above: 10 mg once daily

The total duration of treatment and follow-up for all treatment arms is one year.

Please use the following contact details to request a patient information sheet: Dr Kaninika Basu Maternal and Child Health Sciences Ninewells Hospital and Medical School University of Dundee Dundee DD1 9SY Email: k.basu@dundee.ac.uk Tel: +44 (0)1382 660111

Intervention Type

Drug

**Phase** Not Specified

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

Montelukast, salmeterol, fluticasone propionate

#### Primary outcome measure

Oral montelukast is associated with reduced school absences in comparison to inhaled salmeterol over a period of 1 year in Arg/Arg-16 asthmatic children.

#### Secondary outcome measures

1. Oral montelukast is associated with reduced out-of hours visits/hospital visits or admissions in comparison to inhaled salmeterol over a period of 1 year

2. Oral montelukast is associated with a reduction in airway resistance in comparison to inhaled salmeterol over a period of 1 year

3. Oral montelukast is associated with reduced exhaled nitric oxide levels in comparison to inhaled salmeterol over a period of 1 year

4. Oral montelukast is associated with reduced salivary eosinophilic cationic protein levels in comparison to inhaled salmeterol over a period of 1 year

5. Oral montelukast is associated with improved asthma specific quality-of-life in comparison to inhaled salmeterol over a period of 1 year

6. Oral montelukast is associated with improved morning peak expiratory flow rate in comparison to inhaled salmeterol over a period of 1 year

Overall study start date

01/08/2007

**Completion date** 31/12/2009

# Eligibility

## Key inclusion criteria

All children and adolescents (5 - 18 years, either sex) with asthma in Tayside (Scotland) known: 1. To carry the Arg/Arg-16 genotype, and

2. Currently on inhaled steroids, and

3. Inhaled bronchodilators according to need

Will be telephoned or contacted through home visits to establish if they have had:

1. Any school absences from asthma, or

2. Out-of-hours visits to General Practitioner (GP)/hospital visits or admissions due to asthma over the previous 12 months

Participant type(s) Patient

**Age group** Child

Lower age limit

5 Years

**Upper age limit** 18 Years

**Sex** Both

**Target number of participants** 120

### Key exclusion criteria

The presence of serious respiratory or multi-system disease (e.g. cystic fibrosis, cancer under current treatment)

# Date of first enrolment 01/08/2007

Date of final enrolment 31/12/2009

## Locations

**Countries of recruitment** Scotland

United Kingdom

**Study participating centre Maternal and Child Health Sciences** Dundee United Kingdom DD1 9SY

## Sponsor information

**Organisation** University of Dundee (UK)

**Sponsor details** c/o Mr Simon Temperley Dundee Scotland United Kingdom DD1 4HU

**Sponsor type** University/education

Website http://www.dundee.ac.uk/

ROR https://ror.org/03h2bxq36

## Funder(s)

**Funder type** University/education

**Funder Name** University of Dundee (UK)

#### Funder Name

Merck Sharp & Dohme Limited (MSD) (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

#### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2013		Yes	No