

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

Submission date 18/04/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 31/07/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 09/11/2012	Condition category Respiratory	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00655616

Protocol serial number
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

Study type(s)

Treatment

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):

1. Flixotide Accuhaler (fluticasone propionate) 50 micrograms per blister; 1 blister dose twice daily plus 1 tablet daily of montelukast
2. Flixotide Accuhaler (fluticasone propionate) 100 micrograms per blister; 1 blister dose twice daily plus 1 tablet daily of montelukast
3. Flixotide Accuhaler (fluticasone propionate) 250 micrograms per blister; 1 blister dose twice daily plus 1 tablet daily of montelukast
4. 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:

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Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Montelukast, salmeterol, fluticasone propionate

Primary outcome(s)

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.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

5 years

Upper age limit

18 years

Sex

All

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**

United Kingdom

Scotland

Study participating centre

Maternal and Child Health Sciences

Dundee

United Kingdom

DD1 9SY

Sponsor information

Organisation

University of Dundee (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**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