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

Submission date	Recruitment status	[_] Prospectively registered
18/04/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
31/07/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
09/11/2012	Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Somnath Mukhopadhyay

Contact details
Maternal and Child Health Sciences
Ninewells Hospital and Medical School
Tayside
Dundee
United Kingdom
DD1 9SY
+44 (0)1382 660111 ext. 36297
s.mukhopadhyay@dundee.ac.uk

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):
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:
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