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Does montelukast affect the structural proteins in the sputum of patients with asthma?

Submission date 09/12/2008	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 17/06/2009	**Overall study status** Completed	
Last Edited 24/05/2016	**Condition category** Respiratory	

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
6

Study information

Scientific Title
The effect of montelukast therapy on messenger ribonucleic acid (mRNA) profile of matrix metalloproteinases and their inhibitors in the sputum of patients with asthma

Study objectives

The expression profile of matrix metalloproteinases and their inhibitors is modified by treatment with montelukast.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Norfolk Research Ethics Committee (REC) approved on the 14th April 2009 (ref: 09/H0310/29)

Study design
Single centre open labelled pilot study

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Oral montelukast 10 mg once daily for 8 weeks is given to all patients. Follow-up at 8 weeks.

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome(s)
Induced sputum mRNA of matrix metalloproteinase (MMP) and tissue inhibitors of MMPs (TIMPs), measured before and after 8 weeks of treatment.

Key secondary outcome(s))
No secondary outcome measures

Completion date
01/09/2009

Eligibility

Key inclusion criteria
1. Male or female, aged 18 to 60 years
2. Diagnosed with asthma, defined as episodic chest tightness, wheezing and dyspnoea, cough
3. Non-smoker or ex-smoker for at least 10 years and a smoking history of less than 5 pack years
4. History of asthma symptoms for more than 10 years

5. Receiving as required short acting bronchodilators
6. Post-bronchodilator forced expiratory volume in one second (FEV1) 50 - 100% predicted
7. Evidence of airway calibre reversibility within the previous 12 months: reversibility to salbutamol of 12% following 400 µg inhaled salbutamol, histamine PC20 less than 8 mg/ml, diurnal variation in peak expiratory flow of 20%
8. Able to produce sputum after induction with saline

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
60 years

Sex
All

Key exclusion criteria
1. Cardiac or pulmonary disease other than asthma
2. Respiratory infection defined as fever, nasal/sinus congestion, fatigue, cough, antibiotic use or yellow/green sputum within 4 weeks prior to study
3. Receiving inhaled or oral corticosteroid therapy, long acting Ò2 agonist therapy or leukotriene modifying therapy for the previous 1 month
4. Severe or uncontrolled co-morbid disease
5. Pregnancy or breastfeeding
6. Unable to give written informed consent

Date of first enrolment
01/03/2009

Date of final enrolment
01/09/2009

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

Biomedicine Group
Norwich
United Kingdom
NR4 7TJ

Sponsor information

Organisation
University of East Anglia (UK)

ROR
https://ror.org/026k5mg93

Funder(s)

Funder type
Industry

Funder Name
Merck Sharp & Dohme Ltd (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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes