

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
Registration date 17/06/2009	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 24/05/2016	Condition category Respiratory	☐ Individual participant data ☐ 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

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)

Primary study design

Interventional

Study design

Single centre open labelled pilot study

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 O_2 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