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Understanding chronic cough

Submission date 16/03/2011	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 07/04/2011	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 08/02/2017	**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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Version 2.0

Study information

Scientific Title
Comparing Capsaicin Dose-Response Curves

Acronym
DRC

Study objectives
The shape of capsaicin dose-response curves differ:
1. In healthy volunteers, asthmatics and patients with chronic cough
2. In men and women
These differences may provide insights into important mechanisms that lead to excessive coughing.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North West 7 Research Ethics Committee - Greater Manchester Central approved 19/10/2010

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Chronic cough

Interventions
Two capsaicin cough challenge tests performed:
1. Increasing doses are inhaled up to maximum tolerated dose
2. Doses are inhaled in a random order
3. Number of coughs and urge-to-cough intensity recorded

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Comparison of maximum cough responses between patient groups

Secondary outcome measures
1. Comparison of cough threshold between patient groups
2. Comparison of urge-to-cough threshold between patient groups
3. Comparison of maximum cough responses and cough threshold in men and women

Overall study start date
01/11/2009

Completion date
31/07/2010

Eligibility

Key inclusion criteria
Healthy volunteers
1. Over 18 years old
2. Normal lung function
3. No current or past history of chronic cough or chronic respiratory illness
4. No current or past history of chronic pain, irritable bowel syndrome or chronic headaches
5. No current or past history of psychiatric illness

Asthmatics
1. Over 18 years old
2. Physician diagnosis of asthma
3. Objective evidence of bronchial hyper-reactivity (either positive bronchial provocation test or significant (>12%) reversibility in FEV1 following inhaled bronchodilator)
4. Stable asthma [forced expiratory volume in one second (FEV1) > 75% predicted, no acute exacerbations requiring oral corticosteroids within last 4 weeks]
5. Can safely omit long-acting bronchodilators (if taking)

Chronic Cough Patients
1. Over 18 years old
2. Chronic cough, defined as a cough lasting longer than 8 weeks despite investigation and/or treatment trials for cough variant asthma, post-nasal drip and gastro-oesophageal reflux disease
3. Normal chest x-ray
4. Normal lung function
5. Can safely omit long-acting bronchodilators (if taking)

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

Key exclusion criteria
All participants:
1. Recent upper respiratory tract infection (< 4weeks)
2. Pregnancy or breast-feeding
3. Use of agiotensin converting enzyme (ACE) inhibitors
4. Any centrally acting medication which could alter the sensitivity of the cough reflex
5. History of drug or alcohol abuse
6. Current smoker or ex-smoker with > 10 pack year smoking history

Date of first enrolment
01/11/2009

Date of final enrolment
31/07/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
North West Lung Research Centre
Manchester
United Kingdom
M23 9LT

Sponsor information

Organisation
University Hospitals South Manchester NHS Trust (UK)

Sponsor details
c/o Andrew Maines
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Sponsor type
Not defined

ROR
https://ror.org/00he80998

Funder(s)

Funder type
Research council

Funder Name
Medical Resarch Council (MRC) (UK) (ref: G0900449)

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