

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

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

Comparison of maximum cough responses between patient groups

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

All participants:

1. Recent upper respiratory tract infection (< 4weeks)
2. Pregnancy or breast-feeding
3. Use of angiotensin 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

United Kingdom

England

Study participating centre

North West Lung Research Centre

Manchester

United Kingdom

M23 9LT

Sponsor information

Organisation

University Hospitals South Manchester NHS Trust (UK)

ROR

<https://ror.org/00he80998>

Funder(s)

Funder type

Research council

Funder Name

Medical Research Council (MRC) (UK) (ref: G0900449)

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration

