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Diffuse noxious inhibitory controls in chronic cough

Submission date	Recruitment status	[ ] Prospectively registered
20/12/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
07/04/2011	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
13/02/2017	Respiratory	[ ] 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
DNIC1; G0900449

Study information

Scientific Title
Diffuse Noxious Inhibitory Controls in chronic cough: a randomised, four-way cross-over study of 20 healthy subjects and 20 patients with chronic cough

Acronym
DNIC

Study objectives
1. Inhibitory mechanisms control coughing in healthy subjects, but not in patients with chronic cough
2. Females have less effective inhibitory mechanisms compared to males

Ethics approval required
Old ethics approval format

Ethics approval(s)
North West 6 Research Ethics Committee - Greater Manchester South, 14/12/2010, ref: 10/H1003 /104

Study design
Randomised four-way cross-over study

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

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

Interventions
Basal conditions:
During both blocks of capsaicin inhalation (block 1 and block 2) participants will not place their hand in a water bath and will be instructed to cough freely.

Control conditions:
During both blocks of capsaicin inhalation (block 1 and block 2) participants will place their hand in a non-painful warm water bath (37°C) and will be instructed to cough freely.

Cold water conditions:
During one of the blocks of capsaicin inhalation (block 1 or 2) participants will place their hand in a painful cold water bath (10°C). During the other block participants will place their hand in a non-painful warm water bath (37°C). The order of the blocks is randomised. Participants will cough freely throughout.

Conscious cough suppression conditions:
During one of the blocks (block 1 or 2) participants will place their hand in a non-painful warm water bath (37°C) and will be asked to "try not to cough". During the other block participants will place their hand in a non-painful warm water bath (37°C) and will be instructed to cough freely. The order of the blocks is randomised.

The duration of this clinical trial will range from 2 - 5 weeks.

Intervention Type
Other

Primary outcome measure
Effect of painful cold water bath on cough response, recorded following each of the four randomised interventions. Each intervention will take place at least 48 hours apart.

Secondary outcome measures
1. Effect of conscious cough suppression on cough response
2. Comparison of effects by group and gender

The primary and secondary outcome measures will be recorded following each of the four randomised interventions. Each intervention will take place at least 48 hours apart.

Overall study start date
04/01/2011

Completion date
04/01/2012

Eligibility

Key inclusion criteria
Healthy volunteers:
1. Aged over 18 years old, either sex
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
6. No current history of reflux disease or post-nasal drip syndrome

Chronic cough patients:
1. Aged over 18 years old, either sex

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)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40 (20 healthy volunteers and 20 chronic cough patients)

Key exclusion criteria
1. Recent upper respiratory tract infection (less than 4 weeks)
2. Pregnancy or breastfeeding
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 greater than 10 pack year smoking history

Date of first enrolment
04/01/2011

Date of final enrolment
04/01/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University Hospitals South Manchester
Manchester
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Sponsor information

Organisation
University Hospitals of South Manchester NHS Foundation Trust (UK)

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Sponsor type
Hospital/treatment centre

Website
http://www.uhsm.nhs.uk/Pages/default.aspx

ROR
https://ror.org/00he80998

Funder(s)

Funder type
Research council

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

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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