

Diffuse noxious inhibitory controls in chronic cough

Submission date 20/12/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 07/04/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 13/02/2017	Condition category Respiratory	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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
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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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**

United Kingdom

England

Study participating centre

University Hospitals South Manchester

Manchester

United Kingdom

M23 9LT

Sponsor information**Organisation**

University Hospitals of South Manchester NHS Foundation Trust (UK)

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

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