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A study investigating Autonomic Dysfunction In chronic cough patienTs

Submission date
21/08/2013

Recruitment status
No longer recruiting

Registration date
23/01/2014

Overall study status
Completed

Last Edited
31/01/2019

Condition category
Signs and Symptoms

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Your nervous system allows your body to respond to changes in the environment by sending messages back and forth from the brain to different parts of your body. Your heart rate and blood pressure are controlled by your autonomic nervous system. Your heart rate and blood pressure change throughout the day, often in response to changes in your environment, such as standing up from a sitting position, or a change in temperature. In some people the autonomic nervous system does not always function correctly which can lead to problems such as light headiness or even fainting. Autonomic nervous system dysfunction has previously been studied in patients with other hypersensitivity disorders, such as asthma, but has not been previously studied in patients with chronic cough. This study aims to study autonomic function in people with chronic cough and healthy individuals to see whether there are any differences between the two groups.

Who can participate?
The study aims to recruit 20 chronic cough patients and 10 healthy volunteers with the same age distribution and proportion of males and females in each group.

What does the study involve?
This study involves three visits to the University Hospital of South Manchester. Visit 1 involves measuring and recording heart rate and blood pressure, an electrocardiogram (ECG), completion of three questionnaires designed to understand how coughing affects your daily life, a simple lung function test called spirometry, and fitting of a cough monitor, which is designed to record the number of times you have coughed during the day and how long for. This visit is anticipated to last about 1 hour. Visit 2 is a short visit and involves a cough challenge only, which is a test designed to make you to cough. This visit is anticipated to last about 30 minutes. Visit 3 is anticipated to last about 2 hours and 30 minutes and requires participants to fast for 4 hours prior to their appointment. Tests will be performed which are designed to affect blood pressure and heart rate, both of which will be monitored throughout the visit with respiratory bands, an ECG monitor and a beat-to-beat blood pressure monitor.

What are the possible benefits and risks of participating?
There will be no direct benefit for participants in this study. We hope that the results of this

study will help us to understand the mechanisms of chronic cough. During the study you will be asked to perform a cough challenge which involves inhaling capsaicin, a component of chilli peppers. Capsaicin can cause tightening of the airways, although this is rare. Breathing tests are performed during and after the test to monitor any chest tightening, which is easily treated by inhaling salbutamol (a medication to open up the airways). A number of autonomic function tests will be performed during this study. These tests are designed to cause changes in your blood pressure and heart rate. As such these tests may make you feel light headed or even cause you to faint. If you do feel unwell you must tell a researcher. A doctor will be present during all autonomic function testing.

Where is the study run from?
This is a single centre study being conducted at the University Hospital of South Manchester. Healthy volunteers are being recruited from a list of volunteers stored in the North West Lung Research Centre at the University Hospital of South Manchester and chronic cough patients are being recruited from the tertiary referral cough clinic hosted by the University Hospital of South Manchester.

When is the study starting and how long is it expected to run for?
The study started recruiting in August 2013 and is expected to run until April 2014.

Who is funding the study?
University of Manchester, UK.

Who is the main contact?
Mrs Rachel Dockry, Research Assistant
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Contact information

Type(s)
Scientific

Contact name
Dr Jacky Smith

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Additional identifiers

Protocol serial number
12/AUD/007

Study information

Scientific Title
A study investigating autonomic dysfunction in chronic cough patients

Acronym
AuDyIt

Study objectives
Subjects with chronic cough will show evidence of sub-clinical autonomic dysfunction when compared to a healthy control group.

Note: The trial was initially submitted for ISRCTN registration on 21/08/2013. The ISRCTN registration was delayed due to miscommunication and finalised on 23/01/2014.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North West - Greater Manchester North, 04/03/2013, REC ref.: 13/NW/0148

Study design
Observational case-control single-centre study

Primary study design
Observational

Study type(s)
Other

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

Interventions
This study involves a number of autonomic function tests which are designed to cause changes in your blood pressure and heart rate such as ECG monitoring, beat-to-beat blood pressure monitoring, Valsalva manoeuvre, deep metronomic breathing, voluntary coughing, capsaicin-induced cough, seated to standing test, cold pressor test and head up tilt test.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
The difference in heart rate variability in response to the Valsalva manoeuvre between the chronic cough group and the healthy control group.

Key secondary outcome(s))

1. To compare the heart rate variability response to autonomic function testing between chronic cough and healthy subjects
2. To compare the blood pressure response to autonomic function testing between chronic cough and healthy subjects
3. To compare the scores of the Survey of Autonomic Symptom between chronic cough and healthy subjects

We will be performing beat-to-beat blood pressure analysis on subjects whilst performing deep metronomic breathing, tilt table testing, cold pressor test, voluntary cough and capsaicin-induced cough. We will be comparing the blood pressure and heart rate responses between cases and controls. This is not a longitudinal study and therefore these measurements will be made on one occasion and not repeated at time points.

Completion date
01/04/2014

Eligibility

Key inclusion criteria
1. Chronic cough subjects aged 18 and over or healthy volunteers aged 45 and over
2. Subject must be able to give informed consent
3. Normal spirometry
4. Cough subject only: 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
5. No significant respiratory diseases (except chronic cough in the patient group)
6. No known autonomic function disorders, neuropathy or neurological disorders
7. No history of syncope which is not related to cough
8. Current alcohol consumption exceeding government guidelines

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Asthma, diabetes; cardiovascular disease, hypertension, irritable bowel syndrome (IBS), previous brain injury, history of myocardial infarction or any other disorder deemed unsuitable by the investigator
2. Current smoker or ex smoker (more than 10 pack years) and those still smoking within 6

months of the start of the study
3. Regular intense exercise, i.e. competitive sports
4. Blood pressure over 160/90 or abnormal ECG as determined by a medical doctor on screening
5. Pregnancy or breast-feeding
6. Use of angiotensin-converting-enzyme (ACE) inhibitors
7. Use of centrally acting medications that may affect the cough reflex (pregabalin and opiates may not be taken within 1 week of screening and throughout study)
8. History of drug or alcohol abuse
9. Current, treated depression
10. BMI greater than or equal to 32
11. Subjects taking anti-hypertensives; beta blockers; calcium channel blockers; anticholinergic medications or antidepressant treatment.

Date of first enrolment
05/08/2013

Date of final enrolment
01/04/2014

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
C/o University Hospital of South Manchester NHS Foundation Trust
Manchester
United Kingdom
M23 9LT

Sponsor information

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

ROR
https://ror.org/00he80998

Funder(s)

Funder type
University/education

Funder Name
The University of Manchester (UK)

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?
Basic results		31/01/2019	31/01/2019	No	No
HRA research summary			28/06/2023	No	No