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Ambulatory ECG and Cough Monitoring in Chronic Cough Patients and Healthy Volunteers

Submission date 14/09/2015	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 09/11/2015	**Overall study status** Completed	
Last Edited 25/06/2024	**Condition category** Respiratory	

Plain English summary of protocol

Background and study aims

The autonomic nervous system (ANS) is the part of the nervous system which controls automatic bodily functions, such as breathing and blood pressure. A chronic cough, also known as a persistent cough, is a cough that has lasted for more than 8 weeks. In many cases, it has been found that people suffering from chronic cough also have problems with high blood pressure (hypertension). A possible reason for this could be that the ANS is not controlling bodily functions the way it should do. There may therefore be a link between coughing and other automatic functions such as the heart rate. Heart rate variability (HRV) is a measurement of the time between individual heart beats. As HRV is determined by the ANS, if there is a problem with the way the ANS is functioning then this could affect the HRV. The aim of this study is to investigate the link between coughing and HRV.

Who can participate?

Adults who took part in the COMPASS Phase I study (COMPASS 31 questionnaire) with a chronic cough and age matched healthy controls.

What does the study involve?

Participants who took part in phase 1 of the study (completing the COMPASS 31 questionnaire) and who wish to take part in phase 2, visit the hospital. There, any changes in medical history are checked using a short interview. Participants are then measured and weighed, and then attached to an ambulatory cough monitor and a Holter ECG monitor. These monitors remain in place for 24 hours, to continually collect information about the amount participants are coughing and their heart rate.

What are the possible benefits and risks of participating?

A possible benefit is that the participants are able to have a 24 hour ECG, which has the potential to detect any unknown heart conditions. There are no significant risks of participating, however skin irritation from the sticky pads attached to the monitors may be experienced in some people.

Where is the study run from?

University Hospital of South Manchester (UK)

When is the study starting and how long is it expected to run for?
August 2015 to June 2023

Who is funding the study?
University of Manchester (UK)

Who is the main contact?
Mrs Rachel Dockry

Contact information

Type(s)
Public

Contact name
Mrs Rachel Dockry

Contact details
The Gregson Suite
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
184831

Protocol serial number
15/COM2/001, IRAS 184831

Study information

Scientific Title
COMPASS Phase II: A comparison of HRV measure by Ambulatory ECG and Cough Monitoring in Chronic Cough Patients and Healthy Volunteers

Acronym
COMPASS Phase II

Study objectives
Patients with chronic cough will exhibit abnormal heart rate variability (HRV).

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North West, 04/09/2015, ref: 15/NW/0637

Study design
Single-centre case-control study

Primary study design
Observational

Study type(s)
Other

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

Interventions
Subjects wear both an ambulatory cough monitor and a Holter ECG monitor which will record simultaneously for 24 hours.

Intervention Type
Other

Primary outcome(s)
Heart rate variability (HRV), calculated using the full 24 hour ECG trace recorded from the from the Holter device. A fast Fourier transform (FFT) method is used to investigate the changes in heart rate over the full day, to indicate autonomic activity.

Key secondary outcome(s))
1. Cough count over 24 hours, recorded by the ambulatory cough monitor
2. Association between autonomic symptom score (COMPASS 31 questionnaire from part 1 of the study) and with cough counts and heart rate variability (HRV)

Completion date
30/06/2023

Eligibility

Key inclusion criteria
1. Subjects who completed COMPASS Phase I and gave permission to be contacted by the research team regarding phase 2
2. Over 18 years of age
3. 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
4. No significant respiratory diseases (except chronic cough in the patient group)

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 (within 4 weeks)
2. Asthma; diabetic neuropathy; ischemic heart disease; fibromyalgia; previous brain injury; history of myocardial infarction or any other disorder deemed unsuitable by the investigator
3. Any neurological impairment which may have an effect on autonomic function and is deemed unsuitable by the investigator
4. Currently receiving ACE inhibitor treatment (e.g. lisinopril, perindopril, ramipril)
5. Currently on opiate cough suppressant treatment (e.g. codeine, morphine)
6. Current smoker or ex-smoker > 10 pack years still smoking within 6 months of study

Date of first enrolment
30/09/2015

Date of final enrolment
30/06/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University Hospital of South Manchester
North West Lung Research Centre
Southmoor Road
Wythenshawe
Manchester
United Kingdom
M23 9LT

Sponsor information

Organisation
University Hospital of South Manchester

ROR
https://ror.org/00he80998

Funder(s)

Funder type
University/education

Funder Name
University of Manchester

Alternative Name(s)
University of Manchester in United Kingdom, University of Manchester UK, The University of Manchester, UoM

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date'.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No