

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

<b>Submission date</b> 14/09/2015	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 09/11/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 25/06/2024	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

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

## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

184831

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

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

**Secondary study design**

Case-control study

**Study setting(s)**

Hospital

**Study type(s)**

Other

**Participant information sheet****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 measure**

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.

**Secondary outcome measures**

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)

**Overall study start date**

01/08/2015

**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

### Age group

Adult

### Lower age limit

18 Years

### Sex

Both

### Target number of participants

20 - 40 chronic cough patient and 20 healthy volunteers

### 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

England

United Kingdom

**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

**Sponsor details**  
Research & Development Department  
Southmoor Road  
Wythenshawe  
Manchester  
England  
United Kingdom  
M23 9LT

**Sponsor type**  
Hospital/treatment centre

**Website**  
<http://www.researchdirectoraterg.org.uk/>

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

## **Funder(s)**

**Funder type**  
University/education

**Funder Name**  
University of Manchester

**Alternative Name(s)**

The University of Manchester, University of Manchester UK, University of Manchester in United Kingdom, UoM

### **Funding Body Type**

Government organisation

### **Funding Body Subtype**

Universities (academic only)

### **Location**

United Kingdom

## **Results and Publications**

### **Publication and dissemination plan**

This project forms part of a PhD and as such will be published within a thesis. We also hope to publish the results in a peer review journal. As a team, we publish a newsletter which is available for patients within our clinic and also mailed to volunteers who have expressed an interest in the results of the study in which they have participated.

### **Intention to publish date**

30/06/2025

### **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?
<a href="#">HRA research summary</a>			28/06/2023	No	No