Sensations and triggers of coughing pre- and post-treatment in chronic cough

Submission date 14/09/2022	Recruitment status No longer recruiting	Prospectively registered		
		[X] Protocol		
Registration date 26/09/2022	Overall study status Ongoing	[] Statistical analysis plan		
		[_] Results		
Last Edited 16/04/2025	Condition category Respiratory	Individual participant data		
		[X] Record updated in last year		

Plain English summary of protocol

Background and study aims

The researchers want to look at a new questionnaire for patients with a chronic cough - the TOPIC questionnaire. It is hoped that this questionnaire describes some of the typical symptoms patients experience. The researchers want to see if this questionnaire changes with the treatment of chronic cough in clinic. They want to see if the changes relate to other measures, such as cough scores and number of coughs over 24 hours.

Who can participate?

Patients over the age of 18 years with a chronic cough (over 8 weeks) attending a specialist cough clinic in Manchester

What does the study involve?

Some particular medications (any that cause cough) may need to be reviewed. Patients will then complete questionnaires and wear a cough recorder for 24 hours. Treatment will then be given according to the normal approach in the clinic. Once the cough has improved/stabilised the questionnaires and cough recording will be repeated.

What are the possible benefits and risks of participating? The benefits include furthering our understanding of chronic cough as a condition. There are no risks.

Where is the study run from? Manchester University NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for? January 2019 to September 2025

Who is funding the study? Merck Sharp & Dohme (UK) Who is the main contact? 1. Dr Paul Marsden, cough.research@manchester.ac.uk 2. Cough Research Team General, cough.research@mft.nhs.uk

Contact information

Type(s) Principal Investigator

Contact name Dr Paul Marsden

Contact details Wythenshawe Hospital and Manchester University Manchester United Kingdom M23 9LT +44 (0)1612915921 cough.research@manchester.ac.uk

Additional identifiers

EudraCT/CTIS number Nil known

IRAS number 288299

ClinicalTrials.gov number Nil known

Secondary identifying numbers IRAS 288299, CPMS 54114

Study information

Scientific Title Sensations and Triggers of Coughing pre- and post-treatment in Chronic Cough (STaRR)

Acronym STaRR

Study objectives

It is hypothesized that the sensations associated with chronic cough as captured by the ToPiC questionnaire change following standard treatment for chronic cough. It is also hypothesized that these changes correlate with both objective/subjective measures of cough and cough-specific quality of life and that the ToPiC questionnaire will be able to differentiate between those with refractory chronic cough (RCC) or unexplained chronic cough (UCC) and non-RCC/UCC.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 22/08/2022, North West - Greater Manchester South Research Ethics Committee (3rd Floor, Barlow House, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 (0)207 104 8143; gmsouth. rec@hra.nhs.uk), ref: 22/NW/0210

Study design Observational study

Primary study design Observational

Secondary study design Longitudinal study

Study setting(s) Hospital

Study type(s) Treatment

Participant information sheet See trial outputs table

Health condition(s) or problem(s) studied

Refractory and unexplained chronic cough

Interventions

Subjects will be recruited from the specialist Cough Clinic and undergo the following procedures:

Baseline:

- 1. Cough visual analogue scale (VAS)
- 2. Numerical (Likert) cough severity score
- 3. Cough-related quality of life questionnaire (Leicester Cough Questionnaire [LCQ])
- 4. 24-hour cough monitoring (VitaloJAK)

Subjects will then undergo investigation and treatment according to the North West Cough Network guidelines which have been developed locally and based upon published guidelines and evidence.

Once the end of the algorithm has been reached and/or the cough has reached stability, patients will undergo identical procedures as at baseline.

Intervention Type Other

Primary outcome measure

Characteristics and severity of cough measured using the ToPiC questionnaire score before treatment (Day 1) and after completion of investigation and treatment (3-6 months) after enrolment

Secondary outcome measures

Measured before treatment (Day 1) and after completion of investigation and treatment (3-6 months) after enrolment:

- 1. 24-hour cough frequency measured using VitaloJAK
- 2. Cough-related quality of life measured using the Leicester Cough Questionnaire [LCQ])
- 3. Patient-reported cough severity measured using cough visual analogue scale (VAS)

Overall study start date

01/01/2019

Completion date 30/09/2025

Eligibility

Key inclusion criteria

- 1. Adults over the age of 18 years
- 2. Referred to the tertiary chronic cough clinic
- 3. Non-smokers or ex-smokers <20 pack years and greater than 6 months of abstinence
- 4. Persistent cough of at least 8 weeks duration

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants 100

Total final enrolment

105

Key exclusion criteria

1. Currently taking angiotensin-converting enzyme (ACE) inhibitors

2. Recent history of upper or lower respiratory tract infection or significant change of pulmonary status within 4 weeks of enrolment

3. Current smoker or smoking history >20 pack years

Date of first enrolment 01/09/2022

Date of final enrolment 30/08/2024

Locations

Countries of recruitment England

United Kingdom

Study participating centre Wythenshawe Hospital Southmoor Road Wythenshawe Manchester United Kingdom M23 9LT

Study participating centre South Manchester Ptc (withington) Withington Hospital Nell Lane Manchester United Kingdom M20 2LR

Study participating centre Altrincham Hospital Railway Street Altrincham United Kingdom WA14 2RE

Study participating centre North Tyneside General Hospital Rake Lane North Shields United Kingdom NE29 8NH **Study participating centre Royal Preston Hospital** Sharoe Green Lane North Fulwood Preston United Kingdom PR2 9HT

Sponsor information

Organisation Manchester University NHS Foundation Trust

Sponsor details R&I Department Research Office 1st Floor Nowgen Centre 29 Grafton Street Manchester England United Kingdom M23 9LT +44 (0)161 276 4125 research.sponsor@mft.nhs.uk

Sponsor type Hospital/treatment centre

Website https://mft.nhs.uk/wythenshawe/

ROR https://ror.org/00he80998

Funder(s)

Funder type Industry

Funder Name Merck Sharp and Dohme Alternative Name(s) MSD United Kingdom, Merck Sharp & Dohme, Merck Sharp & Dohme Corp., MSD

Funding Body Type Private sector organisation

Funding Body Subtype For-profit companies (industry)

Location United Kingdom

Results and Publications

Publication and dissemination plan National and international conferences, medical journal, PhD thesis

Intention to publish date 30/12/2025

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?
Participant information sheet	version 2	29/07/2022	16/09/2022	No	Yes
Protocol file	version 2	29/07/2022	16/09/2022	No	No
HRA research summary			28/06/2023	No	No
Participant information sheet	version 5.0	27/09/2023	16/04/2025	No	Yes
Protocol file	version 4.0	27/09/2023	16/04/2025	No	No