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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** Completed	[_] Statistical analysis plan [_] Results
Last Edited 16/04/2025	**Condition category** Respiratory	[_] Individual participant data [_] 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

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Additional identifiers

Integrated Research Application System (IRAS)
288299

Central Portfolio Management System (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

Study type(s)
Treatment

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(s)
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

Key secondary outcome(s))
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)

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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
United Kingdom

England

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

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

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
Participant information sheet	version 2	29/07/2022	16/09/2022	No	Yes
Participant information sheet	version 5.0	27/09/2023	16/04/2025	No	Yes
Protocol file	version 2	29/07/2022	16/09/2022	No	No
Protocol file	version 4.0	27/09/2023	16/04/2025	No	No