ISRCTN13970657 https://doi.org/10.1186/ISRCTN13970657

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

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|---|---|---|
| **Submission date**<br>14/09/2022 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[X] Protocol |
| **Registration date**<br>26/09/2022 | **Overall study status**<br>Completed | [_] Statistical analysis plan<br>[_] Results |
| **Last Edited**<br>16/04/2025 | **Condition category**<br>Respiratory | [_] Individual participant data<br>[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

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Wythenshawe Hospital and Manchester University
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# Additional identifiers

### Clinical Trials Information System (CTIS)
Nil known

### Integrated Research Application System (IRAS)
288299

### ClinicalTrials.gov (NCT)
Nil known

### Protocol serial number
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

## 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 |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |
| Protocol file | version 2 | 29/07/2022 | 16/09/2022 | No | No |

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|---|---|---|---|---|---|
| Protocol file | version 4.0 | 27/09/2023 | 16/04/2025 | No | No |