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An evaluation of the efficacy and safety of SC0032 oral spray in adults with refractory cough or unexplained chronic cough

Submission date
30/01/2026

Recruitment status
Recruiting

Registration date
17/06/2026

Overall study status
Ongoing

Last Edited
17/06/2026

Condition category
Respiratory

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims

A chronic cough is a cough that lasts for more than eight weeks. It affects millions of adults worldwide and can have a major impact on daily life. For some people, the cough continues even after standard treatments have been tried, or no clear cause can be found. This is known as refractory or unexplained chronic cough. People with this condition often experience poor sleep, tiredness, embarrassment in social situations, and anxiety or low mood. There are currently very few effective treatment options available.

Research suggests that people with chronic cough may have airways that are drier and more acidic than normal. These changes may irritate the throat and trigger coughing.

This study is testing a new non-drug device called SC0032. SC0032 is a laryngeal soft mist spray that is inhaled through the mouth. It delivers a fine alkaline salt solution to the throat and windpipe. The spray is designed to gently rehydrate the airway surface and reduce irritation that can trigger coughing.

Earlier small clinical studies using similar spray formulations showed reductions in cough frequency compared with placebo, and no safety concerns were reported. The current version of the spray has been improved to remain stable for longer and to allow more reliable delivery through the mouth.

The aim of this study is to assess the effect of SC0032 in adults with refractory or unexplained chronic cough. The results may help determine whether this type of spray could offer a safe and effective new treatment option for people living with long-lasting cough.

The aim of this study is to investigate a potential new medical device, SC0032, for the treatment of refractory or unexplained chronic cough. Specifically, the study aims to find out whether using SC0032 can reduce how often people cough and improve quality of life for adults living with refractory or unexplained chronic cough.

Who can participate?

Adults aged 18 to 80 years who have been living with refractory or unexplained chronic cough for at least six months may be able to take part in this study.

People will need to be generally healthy apart from their chronic cough and willing to take part in study procedures, such as using the study spray and carrying study equipment to help

measure coughing. All participants will be identified and screened by the research team at the study site, and only those who meet the study eligibility requirements will be invited to take part.
People will not be able to take part if they currently smoke or vape, or stopped smoking within the last six months; have certain lung conditions (such as chronic obstructive pulmonary disease or uncontrolled asthma); have had a recent chest infection; have significant heart disease or other serious medical conditions; are taking certain medications that could affect cough; are currently receiving specialist cough therapy; or live with someone who has a chronic cough.
All participants who choose to take part will be asked to provide written informed consent before any study procedures begin.

What does the study involve?
If you are interested in taking part, you would first enter a screening phase to check whether the study is suitable for you. Taking part in screening does not guarantee that you will continue into the main study.

Screening and run-in period:
The screening phase lasts about two weeks and includes two visits to the study site and a take-home period between visits.
During the first visit, the study team will explain the study in detail and answer any questions you may have. If you agree to take part, you would be asked to sign a consent form. You would then have some routine health checks, such as a physical examination, lung function test, ECG, blood tests, and questionnaires about your cough and quality of life. You would also complete some questionnaires about your cough and how you feel it impacts your life.
You would be given a wearable cough monitor to use at home and trained on how to use it. You would also be given the study spray to use for a short period, along with instructions on how and when to use it.
During the two-week take-home period, you would use the study spray several times a day, wear the cough monitor daily, and complete a brief questionnaire about your cough using an app.
You would then return to the study site for a second visit. The study team will review the information collected during screening to confirm whether you are eligible to continue. You would also complete some questionnaires.

Treatment period and follow-up:
If you are eligible and choose to continue, you would enter the main study, which includes a treatment period lasting about three weeks and a follow-up period lasting about four weeks.
You would be randomly assigned (by chance) to receive either SC0032 or a placebo spray. Neither you nor the study team would know which one you are receiving.
During the treatment period, you would continue to use the assigned spray each day, wear the cough monitor, and complete a questionnaire about your cough on an app.
You would return to the study site at the end of the treatment period so the study team can check your health, collect used devices, and ask about any side effects or concerns. You would also complete some questionnaires.
During the follow-up period, you would continue to wear the cough monitor and complete a questionnaire about your cough on an app.
At the final study visit, you would return the cough monitor and complete final questionnaires and health checks. After this, your participation in the study would end and your doctor would discuss your ongoing care as usual.
Throughout the study, your safety would be monitored, and you can contact the study team at any time if you have questions or experience any problems. Taking part is voluntary, and you can choose to stop at any time without affecting your usual medical care.

What are the possible benefits and risks of participating?
As with any research study, there may be risks or inconveniences that are not yet known. The study team would monitor your health throughout the study, and you would be able to contact them at any time if you have concerns. If the study doctor believes that continuing in the study is no longer in your best interests, you would be withdrawn from the study and advised on your usual care.
Some people may find the study procedures inconvenient or time-consuming. These include attending study visits, using the study spray several times a day, wearing a cough monitor, and completing questionnaires.
As with other medical studies, taking part may need to be declared to some insurance providers. Participants are advised to check whether this could affect any existing or future insurance policies.
You may or may not experience a direct benefit from taking part in this study. Previous small studies suggest that similar spray devices may reduce coughing in some people, but this cannot be guaranteed.
Even if you do not benefit personally, the information collected during this study may help improve understanding of refractory or unexplained chronic cough and support the development of future treatment options for others with this condition.

Where is the study run from?
Sensory Cloud (United States)

When is the study starting and how long is it expected to run for?
March 2026 to December 2026

Who is funding the study?
Sensory Cloud (United States)

Who is the main contact?
Prof. Chung, f.chung@imperial.ac.uk

Contact information

Type(s)
Principal investigator, Public, Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
366449

Study information

Scientific Title
A randomized, double-blind, placebo controlled, parallel arm pilot evaluation to investigate the efficacy and safety of SC0032, a magnesium salt oral spray, in adults with refractory or unexplained chronic cough

Acronym
REACH2

Study objectives
The primary objective of the clinical study is to evaluate the clinical performance of SC0032 vs placebo in reducing 24-hour cough frequency.

Secondary objectives of the study include:
1. To compare the time (days) to onset of response (i.e. ≥30% reduction in cough frequency) for SC0032 and placebo
2. To compare the duration of response for SC0032 and placebo
3. To characterise the clinical performance of SC0032 and placebo on cough bout frequency and characteristics (i.e. total number of cough bouts, mean bout duration, and mean coughs per bout)
4. To assess impact on cough-specific QoL (LCQ)
5. To evaluate the clinical performance of SC0032 and placebo on cough severity (VAS)
6. To evaluate the clinical performance of SC0032 and placebo on global cough severity (PGIS)
7. To evaluate the clinical performance of SC0032 and placebo on patient perceived change (PGIC)
8. To evaluate the clinical performance of SC0032 and placebo on laryngeal hypersensitivity (LHQ)
9. To evaluate the clinical performance of SC0032 and placebo on daily cough severity using a Numerical Rating Scale (NRS)
10. To assess the incidence of treatment-emergent adverse events
11. To assess the severity of treatment-emergent adverse events
12. To assess changes in pulmonary function

Ethics approval required
Ethics approval required

Ethics approval(s)
Submitted 03/02/2026, Office for Research Ethics Committees (NI) (5 Rathdown Walk, Lisburn, BT28 2RF, United Kingdom; +44 2895361400; reca@hscni.net), ref: 26/NI/0025

Primary study design
Interventional

Allocation

Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Parallel

Purpose
Device feasibility, Treatment

Study type(s)

Health condition(s) or problem(s) studied
Refractory Chronic Cough (RCC)

Interventions
This is a pilot, randomized placebo-controlled, parallel-arm study to determine the safety and efficacy of SC0032 in participants with RCC, which will be conducted in accordance with the requirements of EN ISO 14155:2020 + A11; 2024.

There are three parts to this study and an optional fourth part:

1. an optional Usability Sub-Study (which is completed in Visit 1)
2. a 2-week Run-In [screening] Period, during which only placebo is used. Participants will use the placebo aerosol (4 puffs, QID)
3. a 3-week Parallel Arm Period following randomisation to SC0032 or placebo, during which participants will use the randomised aerosol (4, puffs, QID). Randomisation will be performed via an online IRT tool
4. a 4-week Follow-Up Period during which no treatment is given (observational only)

Participants completing the three primary parts of the study will attend four study visits. Participation in the optional Usability sub-study does not require any additional visits. Participants who do not meet criteria for the Parallel-Arm Period at the end of the Run-In period will only be required to attend two study visits and will not receive an active treatment. Participants who discontinue the study prior to completion will be asked to complete an Early Termination Visit.

During the run-in (screening), treatment and follow-up periods, participants cough frequency and severity will be monitored electronically using a research tool (Hyfe cough monitor), and participants will be asked at each visit to the study site to complete PROs to assess the participants improvement in coughing.

Intervention Type
Device

Phase
Phase II

Drug/device/biological/vaccine name(s)
SC0032

Primary outcome(s)
1. Difference in mean % change from baseline in 24-hour cough frequency measured using Hyfe Cough Measure at Days 13-29 of study

Key secondary outcome(s)

Completion date
31/12/2026

Eligibility

Key inclusion criteria
1. Males and females between 18 and 80 years.
2. Capable of giving signed informed consent.
3. Diagnosed with RCC (including unexplained chronic cough) for at least 6 months.
4. At least 8 coughs per hour, 24-hour cough frequency during the 14-day Run-In Period.
5. Score ≥ 40 mm on cough severity VAS at Screening.
6. Normal FEV1/FVC (greater than 80% of predicted value).
7. A negative test for COVID-19.
8. Women of child-bearing potential and men must agree to use a highly effective contraception method during the study and for at least 14 days after the last dose.
9. Willing to carry study-related equipment as required for the study (e.g. cough monitor, phone).

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
80 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Current smoker/vaper (all forms of smoking and inhaled substances, including cannabis /tobacco smoke and nicotine vapours) or individuals who have given up smoking within the past 6 months, or those with >20 pack-year smoking history.
2. Diagnosis of Chronic Obstructive Pulmonary Disease (COPD), bronchiectasis, idiopathic pulmonary fibrosis, uncontrolled asthma or other serious pulmonary disease.

3. Respiratory tract infection within 4 weeks before screening.
4. History of malignancy in the last 5 years, unless it is a non-serious skin cancer.
5. History of moderate or severe alcohol or drug use disorder within the last 3 years.
6. Opioid use with in the 7 days prior to screening.
7. History of a positive serologic test for hepatitis B virus surface antigen, or hepatitis C virus.
8. Previous participation in a clinical trial in the last 30 days or 6-half half-lives of test drug activity.
9. Current participation in or completion of speech language therapy intervention therapy for chronic cough within 8 weeks prior to screening.
10. Use of Prohibited medications: anti-tussive therapy, systemic corticosteroids, ACE inhibitors, opioids.
11. Gabapentin and pregabalin are prohibited unless they are being administered for treatment of a condition other than RCC and have been on a stable dose of that medication for at least 6 weeks prior to screening and plan to remain on that dose for the duration of the study.
12. Tricyclic antidepressants are prohibited unless they are being administered for treatment of a condition other than RCC and have been on a stable dose of that medication for at least 12 weeks prior to screening and plan to remain on that dose for the duration of the study.
13. Beta blockers are prohibited unless they are on a stable dose for at least 6 weeks prior to screening.
14. Use of dietary supplements containing magnesium for the duration of the study.
15. History of myocardial infarction or other cardiac disorders as follows:
* History of any of the following within 6 months prior to screening, myocardial infarction, stroke or transient ischemic attack, coronary revascularization (PCI or CABG), or heart failure.
* History of clinically significant arrhythmias, poorly controlled hypertension.
* Any condition that, in the opinion of the investigator, places the participant at high risk for an acute cardiovascular event including but not limited to: angina, symptomatic peripheral arterial disease, severe valvular heart disease, planned
cardiovascular intervention or surgery during the study period, baseline QTc interval >450 ms (men) or >470 ms (women), or any clinically significant ECG abnormality as determined by the Investigator.
16. History of any clinically significant or psychiatric condition that, in the eyes of the Investigator or designee, would not be suitable for this study. Or if, in the eyes of the Investigator or designee may prove non-compliant to study procedures.
17. Spouses or other family members with a chronic cough in the household.
18. Living and working in an excessively loud workplace (e.g. building site).

Date of first enrolment
31/03/2026

Date of final enrolment
30/11/2026

Locations

Countries of recruitment
United Kingdom

England

Northern Ireland

Study participating centre
Kings College Hospital
Chest Unit, Cheyne Wing, Second Floor, Denmark Hill
London
England
SE5 9RS

Study participating centre
The Wellcome Trust - Wolfson Northern Ireland
Clinical Research Facility, U-Floor, Belfast City Hospital, Lisburn Road
Belfast
Northern Ireland
BT9 7AB

Study participating centre
Royal Brompton & Harefield Hospital Clinical Research Centre
Guys & St. Thomas' Trust, Fulham Road
London
England
SW3

Sponsor information

Organisation
Sensory Cloud (United States)

ROR
https://ror.org/01vny5262

Funder(s)

Funder type

Funder Name
Sensory Cloud Inc (United States)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available