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Evaluation of N-Tidal in primary care COPD diagnosis

Submission date
20/05/2025

Recruitment status
Recruiting

Registration date
17/06/2025

Overall study status
Ongoing

Last Edited
19/06/2025

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
CORMORANT is a study looking at whether a new device called N-Tidal can help doctors diagnose chronic obstructive pulmonary disease (COPD) more accurately. This could mean better treatment for patients and help save money for the NHS. COPD is common, but many people do not know they have it. In the UK almost half of people affected have not been diagnosed. Spirometry is the current standard test used by healthcare professionals to help diagnose COPD, it takes time, and requires specialist training to operate, and understand the results. At the moment spirometry testing is not available to all people around the UK, or there are very long waiting times. Prompt diagnosis of COPD is important because it means people can start treatments to reduce their symptoms, and stop them worsening, much sooner. We therefore want to research whether there are new tests which could be used to diagnose COPD instead of spirometry. The company TidalSense has built an easy-to-use device called N-Tidal Diagnose. Patients breathe in and out normally into an N-Tidal Handset for 75 seconds, which measures a gas that everyone breathes out called Carbon Dioxide (CO2). The N-Tidal Handset is CE marked which means that the product complies with European law with regards to medical devices. The N-Tidal Diagnose computer program can distinguish between how the changes in the level of CO2 in the breath over time are different between those with and without and COPD. This allows us to tell how likely it is that that person has COPD.

CORMORANT will gather evidence on the value of N-Tidal Diagnose in primary care, the setting where it would be most used. The team will:
1. Test the accuracy of N-Tidal Diagnose in patients who are not yet diagnosed, but are suspected of having COPD.
2. Gather information from healthcare professionals via surveys and interviews to understand how COPD is currently diagnosed, including costs.
3. Carry out analysis to understand the costs and benefits of spirometry and N-Tidal Diagnose. This will help understand how N-Tidal Diagnose can best be used in the NHS to maximise its positive impact.
4. Assess the usability and interpretability of N-Tidal Diagnose using interviews and focus groups in order to identify and eliminate any potential difficulties in adopting the system.

Who can participate?
Anyone aged 35 years or older and has been booked to have a spirometry test to help to diagnose the cause of their breathing symptoms, and COPD might potentially be the cause may be eligible to participate.

What does the study involve?
Firstly we will ask you to sign a consent form if you are happy to take part. This will be an electronic consent form and we will email you a copy. Next, we will ask you to complete a baseline questionnaire, including your medical history related to your breathing and general health. This should take around 20 minutes. Your spirometry test visit will take place as normal, but we will ask you to do an additional test, using the N-Tidal Diagnose device as well. The results from both of these tests will be recorded for the study. At the end of your test visit we will ask some questions about how you have found N-Tidal Diagnose and spirometry. Finally, We will collect some information from your medical notes shortly after you enter into the study, as well as what your diagnosis from the spirometry test was once your test results have been looked at by your health care professional.

What are the possible benefits and risks of participating?
The main advantage of taking part is an opportunity for you to contribute to research that may improve how COPD is diagnosed in primary care. We do not yet know whether the N-Tidal Diagnose will improve diagnosis and thus the care for patients with potential COPD; that is why we are doing this research. The study is considered very low risk. Participants will be asked to breathe in and out normally into the N-Tidal handset for 75 seconds. The N-Tidal handset has been used thousands of times in studies before and no safety concerns have been found. Each participant uses a clean mouthpiece so there is no additional risk of infection.

Where is the study run from?
University of Oxford (UK)

When is the study starting and how long is it expected to run for?
July 2024 to September 2026

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK).

Who is the main contact?
Charlotte.latimer-Bell@phc.ox.ac.uk

Contact information

Type(s)
Public, Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
329554

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 56530, NIHR206532

Study information

Scientific Title
COPD tRansforMation of diagnOstic pathways in pRimary cAre using N-Tidal

Acronym
CORMORANT

Study objectives
Determine diagnostic performance of N-Tidal Diagnose for the diagnosis of COPD in a primary care population

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 11/04/2025, South Central - Oxford A Research Ethics Committee (Ground Floor, Temple Quay House, 2 The Square, Bristol, BS1 6PN, United Kingdom; +44 207 104 8118; oxforda.rec@hra.nhs.uk), ref: 25/SC/0103

Study design
Post-market diagnostic accuracy study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Chronic Obstructive Pulmonary Disease

Interventions
The study is designed so that every participant completes both the standard diagnostic test (spirometry) and the new test (N-Tidal). They will answer some questions about themselves and why they are being tested, but there will be no follow-up visits or further appointments.

When a potential participant presents with respiratory symptoms that could potentially be COPD and is referred for a spirometry test appointment for diagnosis, research sites will also give the participant the Participant Information Sheet (PIS). This can be presented to them on paper or electronically. After reading the information about the study, if the participant is happy to consent, they will be able to do so electronically and will be prompted to complete a short baseline questionnaire. Part of the consent form/PIS also outlines our embedded qualitative sub-study interviews, which are optional.

For the diagnostic tests, the participant will complete their routine spirometry appointment as normal. For the study, they will also complete an additional test using N-Tidal. After participants have completed spirometry and N-Tidal, we ask them to complete Visual Analogue Scores about comfort and ease of use, to assess the acceptability of the two tests.

If the participant is also happy to take part in the qualitative interviews, they can indicate "yes" to the optional section on the main consent form regarding being contacted for an additional optional qualitative interview. If they are happy to be contacted, the research team will reach out to confirm this consent and organise a time for the interview. The research team will purposively target participants who have given particularly high or low acceptance scores in relation to the device use at their appointment and contact them about doing an interview. We also want to select the sample using a number of other parameters such as age, gender, location, etc., in order to achieve as much diversity as possible.

The participant would have an audio-recorded interview (at a time and date that suited them) about their experience with N-Tidal and spirometry. During this recorded interview, the participant’s remote verbal consent would be recorded by the interviewer on the relevant sub-study qualitative interview consent form.

This is the end of the active participation for participants.

The research team would later complete some questions about the outcomes from the tests, including whether the patient was diagnosed with COPD.

We will also conduct qualitative interviews with healthcare professionals who have been involved in the delivery of the study at study sites, in order to find out more about their experiences of using N-Tidal Diagnose and how they could see it potentially being introduced into their current system, to inform implementation.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Diagnostic performance of N-Tidal Diagnose for the diagnosis of COPD measured using N-Tidal and spirometry at study visit and decided by consensus at end of study

Key secondary outcome(s))
1. Diagnostic accuracy (PPV, NPV) of N-Tidal Diagnose is measured using comparison to consensus diagnosis at end of study
2. Diagnostic accuracy (PPV, NPV) of usual care diagnosis is measured using comparison to consensus diagnosis at end of study
3. Diagnostic accuracy (sensitivity, specificity, PPV, NPV) of N-Tidal Diagnose prediction categories is measured using comparison to consensus diagnosis at end of study
4. Feasibility and acceptability to clinicians and patients is measured using Visual Analogue Score following N-Tidal and spirometry at study visit
5. Feasibility and acceptability to clinicians and patients is measured using thematic analysis of semi-structured interviews with participating clinicians and participants post-recruitment
6. Quality of primary care spirometry is measured using percentage of participants with adequate spirometry performed according to ARTP guidelines determined by independent quality assessment at end of study
7. Quality of primary care spirometry is measured using descriptive data on spirometry quality control and training procedures collected during site set-up
8. Quality of primary care spirometry is measured using thematic analysis of semi-structured interviews with participating primary care clinicians post-recruitment
9. Quality of N-Tidal Diagnose data capture is measured using percentage of participants with adequate N-Tidal Handset breath record capture sufficient to generate a diagnostic output using N-Tidal Diagnose software at study visit

Completion date
01/09/2026

Eligibility

Key inclusion criteria
1. Participant is willing and able to give informed consent for participation in the study
2. Participant is aged 35 years old or over
3. Diagnostic spirometry has been requested by their clinician where COPD is a potential diagnosis (even if it is not necessarily the most likely)

Inclusion in the qualitative sub study:
1. Participants in the main study
2. Consented to be contacted regarding the sub-study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
35 years

Sex
All

Key exclusion criteria
1. Participants who have previously had COPD confirmed by spirometry (participants who are having repeat spirometry as part of diagnosis can be included).
2. Participants who, in the opinion of the chief investigator, or their delegate, are unlikely to comply with the requirements of the study.
3. According to the recruiting clinician, participants unable to give fully informed consent.
4. According to the recruiting clinician, participants who are acutely unwell, e.g. requiring hospitalisation
5. Patients without potential COPD i.e. COPD is extremely unlikely as a diagnosis.
6. Patients unable to breathe through their mouths e.g. tracheostomy patients.
7. Participant who have already participated in the study.

Date of first enrolment
01/06/2025

Date of final enrolment
01/03/2026

Locations

Countries of recruitment
United Kingdom

England

Wales

Study participating centre
East Midlands RRDN
Leicester Royal Infirmary

Infirmary Square
Leicester
United Kingdom
LE1 5WW

Study participating centre
East of England RRDN
Norfolk & Norwich University Hosp'
Colney Lane
Colney
Norwich
United Kingdom
NR4 7UY

Study participating centre
North East and North Cumbria RRDN
Freeman Hospital
Freeman Road
High Heaton
Newcastle upon Tyne
United Kingdom
NE7 7DN

Study participating centre
North London RRDN
The Royal London Hospital
Whitechapel Road
Whitechapel
London
United Kingdom
E1 1BB

Study participating centre
North West RRDN
Cobbett House
Manchester Royal Infirmary
Oxford Road
Manchester
United Kingdom
M13 9WL

Study participating centre
South Central RRDN
Southampton General Hospital
Tremona Road
Southampton
United Kingdom
SO16 6YD

Study participating centre
South East RRDN
Royal Surrey County Hospital Guildford
Egerton Road
Guildford
United Kingdom
GU2 7XX

Study participating centre
South London RRDN
Guy's & St Thomas Hospital
Westminster Bridge Road
London
United Kingdom
SE1 7EH

Study participating centre
South West Central RRDN
University Hospitals Bristol and Weston NHS Foundation Trust
Trust Headquarters
Marlborough Street
Bristol
United Kingdom
BS1 3NU

Study participating centre
South West Peninsula RRDN
Royal Devon University NHS Ft
Barrack Road
Exeter
United Kingdom
EX2 5DW

Study participating centre
West Midlands RRDN
New Cross Hospital
Wolverhampton Road
Heath Town
Wolverhampton
United Kingdom
WV10 0QP

Study participating centre
Yorkshire and Humber RRDN
St. James's University Hospital
Beckett Street
Leeds
United Kingdom
LS9 7TF

Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF)

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be 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 1.1	11/04/2025	21/05/2025	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes