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Testing a breathing app for patients in the emergency room

Submission date 26/08/2025	**Recruitment status** Not yet recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 28/08/2025	**Overall study status** Ongoing	
Last Edited 28/08/2025	**Condition category** Respiratory	

Plain English summary of protocol

Background and study aims
This study is looking at a new device to measure aspects of breathing and heart rate. We want to test whether the new device works as well as traditional equipment. The new device is a smartphone application (app) which uses the video camera function. If the new device works as well as the standard methods, it could help doctors to better monitor and treat patients with breathing and heart diseases in the future.

Who can participate?
Males and females, aged 18 years and above, presenting at the Emergency Department at Addenbrooke's Hospital in Cambridge

What does the study involve?
You will be shown the new device and standard equipment. You will use the new app to measure your breathing over a 1-minute period. At the same time the nurse will count your number of breaths. This will be done three times. Next, the doctor or nurse will use the standard equipment (called a spirometer) to measure your breathing. This will be done three times. Then you will use the new device to measure your heart rate over a 1-minute period. At the same time the nurse will use standard equipment (called a pulse oximeter) to measure your heart rate. This will be done three times. Lastly, you will be given a short questionnaire with seven simple questions to say what you thought of using the new app.

What are the possible benefits and risks of participating?
There are no particular advantages of taking part in the study. Your participation is entirely voluntary, and there is no payment for taking part. Your participation may help to bring about a beneficial new way to monitor patients with disorders or diseases that affect their breathing, possibly preventing hospital admissions and bringing about earlier treatment if their disease flares up.
The app uses the smartphone camera to perform a simple non-invasive scan so there are no expected risks to you. If you have any technical problems or difficulties using the app, you may feel frustrated or anxious, but the study staff will always be on-hand to help. To help the app

function correctly, we will use tape to secure a small marker to the back of each of your hands. There is a very low chance of skin reaction to the tape but if that did happen, a cold compress can be used, or calamine lotion to relieve any swelling or itchiness.

Where is the study run from?
Addenbrooke's Hospital (UK)

When is the study starting and how long is it expected to run for?
August 2025 to December 2025

Who is funding the study?
electronRx Ltd (UK)

Who is the main contact?
Dr Bipin Patel (CEO of electronRx), admin@electronrx.com

Study website
http://electronrx.com

Contact information

Type(s)
Principal Investigator

Contact name
Dr Adrian Boyle

Contact details
Emergency Department
Addenbrooke's Hospital
Cambridge Biomedical Campus
Hills Road
Cambridge
United Kingdom
CB2 0QQ
+44 (0)1223 596145
adrianboyle@nhs.net

Type(s)
Scientific

Contact name
Dr Bipin Patel

Contact details
electronRx Ltd
Eagle Labs
28 Chesterton Road
Cambridge
United Kingdom
CB4 3AZ

+44 (0)1223 944358
admin@electronrx.com

Type(s)
Public

Contact name
Dr Adrian Boyle

Contact details
Emergency Department
Addenbrooke's Hospital
Cambridge Biomedical Campus
Hills Road
Cambridge
United Kingdom
CB2 0QQ
+44 (0)1223 596145
adrianboyle@nhs.net

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
360871

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
F006-REG-AD/GB-25

Study information

Scientific Title
CLinical Evaluation of a mobile App-based Respiratory device in the Emergency Department setting (CLEAR-ED)

Acronym
CLEAR-ED

Study objectives
The primary objectives of this study are to evaluate the agreement and usability of a new device, namely purpleDx smartphone application which uses video technology to measure patients' peak expiratory flow, forced expiratory volume in one second, respiratory rate and heart rate. Results obtained using the purpleDx app will be compared to those measured using standard clinical reference methods during a single patient encounter in an Emergency Department setting.

The secondary objectives are to demonstrate the safety of the purpleDx app and determine any subject subgroups or conditions of use of the new device that impair the quality or reliability of data.

Ethics approval required
Ethics approval required

Ethics approval(s)
Submitted 08/08/2025, East of England - Cambridgeshire and Hertfordshire Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8096, +44 (0)207 104 8194, +44 (0)207 104 8269; cambsandherts.rec@hra.nhs.uk), ref: 25/EE/0187

Study design
Single-centre single-visit study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Respiratory disease

Interventions
There is no drug or other treatment involved in this study. It is a study to assess a new medical device compared to standard equipment.

Once a participant has signed the Informed Consent form, they will be shown the new device and standard equipment. They will use the new device (purpleDx smartphone application) to measure their breathing over a 1-minute period. At the same time the nurse will count the number of breaths. This will be done three times. Next, the doctor or nurse will use the standard equipment (called a spirometer) to measure their breathing. This will be done three times. Then participants will use the new device to measure their heart rate over a 1-minute period. At the same time the nurse will use standard equipment (called a pulse oximeter) to measure their heart rate. This will be done three times. Lastly, participants will be given a short questionnaire with seven simple questions to say what they thought of using the new app.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
purpleDx smartphone application

Primary outcome measure
Peak expiratory flow measured by conventional and novel medical devices at a single visit

Secondary outcome measures
1. Forced Expiratory Volume in one second (FEV1), heart rate and respiratory rate measured by conventional and novel medical devices at a single visit
2. The ease of using the novel medical device measured by a simple Likert-scale questionnaire at a single visit
3. The safety of the novel medical device assessed by evaluation of adverse events at a single visit
4. Patients and/or conditions not suitable for assessment by the novel medical device, determined by evaluation of missing, inaccurate and unreliable measurements produced by using the novel medical device at a single visit

Overall study start date
08/08/2025

Completion date
31/12/2025

Eligibility

Key inclusion criteria
1. Male or female
2. Aged 18 years and above, presenting to Addenbrooke's Hospital Emergency Department
3. Able to read/understand/write in English
4. With or without a medical diagnosis of respiratory or cardiopulmonary condition/s

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

125 - 150 participants maximum

Key exclusion criteria
1. Unable to sit up
2. Determined not to have capacity to provide consent to participate in the study
3. Known pregnancy in women of child-bearing potential
4. Unable to comply with the requirements of the investigation in any way
4. Prisoners

Date of first enrolment
02/10/2025

Date of final enrolment
31/12/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Cambridge University Hospitals NHS Foundation Trust
Addenbrooke's Hospital
Emergency Department
Box 87
Cambridge Biomedical Campus
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Sponsor information

Organisation
electronRx Ltd

Sponsor details
Eagle Labs
28 Chesterton Road
Cambridge
England
United Kingdom

CB4 3AZ
+44 (0)1223 944358
admin@electronrx.com

Sponsor type
Industry

Website
https://electronrx.com

Funder(s)

Funder type
Industry

Funder Name
electronRx Ltd

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
31/12/2026

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