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Can a new breathing device help people in hospital with severe flare ups of chronic lung disease clear mucus and breathe more easily?

Submission date
26/04/2026

Recruitment status
Recruiting

Registration date
05/05/2026

Overall study status
Ongoing

Last Edited
30/04/2026

Condition category
Respiratory

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Principal investigator, Public, Scientific

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Additional identifiers

Study information

Scientific Title

Feasibility and benefits of an oscillatory negative-pressure device for secretion mobilization in patients hospitalized with acute COPD exacerbation - a randomized controlled trial

Study objectives
The aim of this study was to assess the feasibility and clinical effects of adding an oscillatory negative-pressure device to conventional respiratory physiotherapy in patients hospitalized for an acute exacerbation of COPD with secretion retention, compared with respiratory physiotherapy combined with a sham procedure.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 14/05/2024, Comissão de ética da ULSAAVE (Hospital da Senhora da Oliveira, Guimarães. Comissão de Ética Rua dos Cutileiros, Creixomil, Guimarães, 4835-044, Portugal; +351 253540330; comissaoetica@ulsaave.min-saude.pt), ref: 45/2024

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Parallel

Purpose
Device feasibility

Study type(s)

Health condition(s) or problem(s) studied
Patients hospitalized with acute exacerbation of COPD

Interventions
Participants will be recruited by the attending physician in collaboration with a physiatrist, who confirmed the indication for respiratory rehabilitation. An initial interview will be conducted by one of the investigators to verify eligibility criteria and obtain written informed consent.

After consent is obtained, the baseline assessment (Assessment 0) will be performed and recorded in the Case Report Form. In this first assessment, demographic data, clinical history and clinical evaluation (Vital signs, respiratory simptoms, CAT, Leicester acute) will be registered.

Participants will then be randomized to either the intervention group or the control group using appropriate randomization software (Randomizer®) making a computer-generated allocation sequence.

The control group will receive conventional respiratory physiotherapy (breathing retraining, controlled inspiratory slow breathing, Slow open glottis expirations, huffing and cough) combined with a sham procedure using the Semiox® device, while the intervention group will reveive similar respiratory physiotherapy combined with the Semiox® oscillatory negative-pressure device.

Interventions will be carried out once a day by the principal investigator, an experienced physiotherapist, with the agreement of the attending physician.

Intervention Type
Device

Phase
Phase II/III

Drug/device/biological/vaccine name(s)
Semiox® oscillatory negative-pressure device.

Primary outcome(s)
1. Sputum Weight (g) measured using a precision balance at 1 hour after treatment

Key secondary outcome(s))
1. COPD Impact (CAT) measured using CAT score at Every 3 days until study discharge

2. Cough-Related Quality of Life (LCQ-acute) measured using Leicester cough questionnaire acute score at Every 3 days until study discharge

3. Length of hospital stay (days) measured using Patient records at End of hospitalization

Completion date
31/12/2026

Eligibility

Key inclusion criteria
1. Patient with confirmed diagnosis of COPD
2. Hospitalized with respiratory onset
3. With an increase of his usual secretion production

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit

18 years

Upper age limit
100 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Hemodynamic instability requiring vasopressor support
2. Severe respiratory failure defined as $PaO_2/FiO_2 < 100$
3. Respiratory failure requiring a fraction of inspired oxygen (FiO_2) > 60%
4. Altered level of consciousness or inability to cooperate with the intervention
5. Untreated or undrained pneumothorax
6. Massive hemoptysis
7. Unstable cardiovascular disease (e.g., acute coronary syndrome, uncontrolled arrhythmias)
8. Any clinical condition requiring strict bed rest or contraindicating participation in respiratory physiotherapy

Date of first enrolment
01/11/2024

Date of final enrolment
20/12/2026

Locations

Countries of recruitment
Portugal

Sponsor information

Organisation
Unidade Local de Saude do Alto Ave

ROR
https://ror.org/049cs4442

Funder(s)

Funder type

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			30/04/2026	No	No