# A40 EFL Registry: A Multicenter Prospective Study to Determine the Role of EFL in Patients with Chronic Obstructive Pulmonary Disease (COPD) Receiving Home Mechanical Ventilation Protocol ID: SRC_HRC_VectorEURegistry_2019_10820

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a. To determine what proportion of COPD patients demonstrate EFL during NIV useb. To determine the range of EPAP necessary to overcome EFLc. To determine longitudinal change of EFL with time and interaction with exacerbationd. To describe the…

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| **Ethical review** | Approved WMO |
| **Status** | Pending |
| **Health condition type** | Bronchial disorders (excl neoplasms) |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON56616

**Source**
ToetsingOnline

**Brief title**
A40 EFL

### Condition

- Bronchial disorders (excl neoplasms)

**Synonym**
COPD, emphysema

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Philips
**Source(s) of monetary or material Support:** Philips BV.

## Intervention

**Keyword:** COPD, Expiratory flow limitation, Home Mechanical Ventilation, Non-invasieve ventilation

## Outcome measures

### Primary outcome

Overall Prevalence of EFL in Ventilated hypercapnic COPD patients, as defined

as the percentage participants exhibiting a DeltaXrs value greater than or

equal to 2.8 at study initiation and at 6 months post therapy.

### Secondary outcome

Descriptive outcomes with respect to:

- the range of EPAP necessary to overcome EFL

- longitudinal change of EFL with time and preceding an COPD exacerbation

- the phenotypic characteristics of COPD most associated with nocturnal EFL

- Effect of EFL-titrated NIV on quality of life, dyspnea, arterial blood gases,

exercise tolerance, patient comfort, lung function, ventilatory efficacy and

patient-ventilator asynchrony, patient effort, and lung inflation.

# Study description

### Background summary

A key physiologic feature of chronic obstructive pulmonary disease is

expiratory flow limitation 1, which occurs because of loss of elastic recoil in turn arising from alveolar damage. This commonly occurs when sufficiently severe gas trapping occurs leading to hyperinflation. By placing the patient on an unfavorable portion of the pressure-volume curve, such patients become harder to ventilate and may experience more side effects, as a consequence.

## Study objective

a. To determine what proportion of COPD patients demonstrate EFL during NIV use
b. To determine the range of EPAP necessary to overcome EFL
c. To determine longitudinal change of EFL with time and interaction with exacerbation
d. To describe the phenotypic characteristics of COPD most associated with nocturnal EFL
e. To determine physiological and clinical effects of EFL-titrated NIV

## Study design

Prospective six-month observational multicenter registry study

## Intervention

EFL-titrated NIV with the A40 machine

## Study burden and risks

The risk benefit analysis for the A40 EFL should be considered in comparison to the standard of care which would be the A40 (or equivalent device from another manufacturer). In that context the proposed benefits of the A40 EFL are more efficient ventilation which should be manifest as better adherence because of improved comfort, and/or better control of hypercapnia.
The EFL mode is anticipated to expose the patients to higher levels of EPAP. Since NIV devices may have an increased risk for aspiration of gastric contents, increase in symptoms of sinusitis or otitis media, and decrease in blood pressure due to a decrease in cardiac output, it is conceptually possible the risks of these events may be increased. However these are thought to be minimal risks of using the EFL mode. Furthermore, patients with known heart failure are excluded. Theoretically, initiation period could be longer (or shorter) because a new mode has to be initiated. Patients currently on NIV may find BiPAP A-40 EFL to be less comfortable than their previous NIV, but this is not a real medical risk, since they can revert to their prior device. Should side effects occur during the course of the study, they will be recorded, allowing quantification of the risk for future product use. Significant adverse events will be reported to the local Research Ethics Committee.

Participation in the trial does not lead to additional visits compared to regular care. The following additional tests will be performed:
- a urine pregnancy test for woman in the childbearing age
- the mMRC dyspnea scoring list and the COPD assessment test at baseline and at 6 months
- a 6-minute waking test at baseline and at 6 months
- EFL titration at baseline and at 6 months
- a HRCT at baseline and at 6 months
- non-invasive measurements of respiratory muscle activity and lung inflation during the admission and follow-up.

## Contacts

**Public**
Philips

Golden Mile Highway 1
Monroeville 1740
US
**Scientific**
Philips

Golden Mile Highway 1
Monroeville 1740
US

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

## Inclusion criteria

COPD (FEV1 <60% predicted and FEV1/VC < 0.7)
Age > 40 years
Chronic hypercapnia (daytime PaCO2 > 6.0 kPa)
No Clinical diagnosis of OSA
Smoking history > 10 pack year
BMI <= 35kg/m2

## Exclusion criteria

Hypercapnic respiratory acidosis defined as pH <7.35
Acute coronary syndrome and unstable angina
Cognitive impairment that would prevent informed consent into the trial and/or inability to comply with the protocol
Patients undergoing renal replacement therapy
Patients with serious comorbidities confirming prognosis likely to be less than 12-months
Pregnant
CHF with EF less than 45% determined by Echo if available

# Study design

## Design

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| Study phase: | 4 |
| Study type: | Interventional |
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Treatment |

## Recruitment

NL

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|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-10-2022 |
| Enrollment: | 20 |
| Type: | Anticipated |

### Medical products/devices used

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|---|---|
| Generic name: | A40 EFL |
| Registration: | Yes - CE intended use |

## Ethics review

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| Approved WMO Date: | 26-08-2022 |
| Application type: | First submission |
| Review commission: | METC Universitair Medisch Centrum Groningen (Groningen) |

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

| Register | ID |
|---|---|
| Other | ClinicalTrials.gov: NCT04419428 |
| CCMO | NL75723.042.22 |