# Calibration of Esophageal Balloon catheter in spontaneous and mandatory mechanical ventilation.

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To obtain the best filling pressure of the Pes catheter in spontaneous mechanical ventilation, to obtain the esophagus elastance in spontaneous mechanical ventilation, and to compare the best filling pressures between the two modes (spontaneous and...

| | |
|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Pending |
| **Health condition type** | Other condition |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON56902

**Source**
ToetsingOnline

**Brief title**
PesCA

### Condition

- Other condition
- Respiratory disorders NEC

**Synonym**
Acute respiratory failure, ARDS, everybody ventilated > 24 hrs.

**Health condition**

Alle aandoeningen waarvoor beademing > 24 uur noodzakelijk is

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Leids Universitair Medisch Centrum
**Source(s) of monetary or material Support:** Hamilton Medical, Zwitserland,Samenwerking met Hamilton Medical

## Intervention

**Keyword:** Esophageal catheter, Mechanical Ventilation, Transpulmonary

## Outcome measures

### Primary outcome

Pressures of the Pes catheter at different filling volumes; Best filling

pressure, Derived elastance of esophagus.

### Secondary outcome

Not applicable

# Study description

### Background summary

Calibration of the esophageal balloon catheter (Pes) is important for the right interpretation of the derived transpulmonary pressures during mechanical ventilation. Calibration of the Pes catheter has only been validated in mandatory ventilation but not in support modes in which the patient triggers the ventilator and exhibits spontaneous breathing activity. Because the forces in the thoracic cage are very different between the two modes it is to be expected that the calibration process yields different filling volumes and therefore to a different calibration approach. This would lead to a more reliable filling volume in spontaneous mechanical ventilation and mor reliable derivation of transpulmonary pressure and therefore to a better treatment of patients.

### Study objective

To obtain the best filling pressure of the Pes catheter in spontaneous mechanical ventilation, to obtain the esophagus elastance in spontaneous mechanical ventilation, and to compare the best filling pressures between the

two modes (spontaneous and mandatory ventilation).

### Study design

Use a standardized calibration protocol to obtain the best filling pressure in both ventilator modes. The first calibration measurement will be in spontaneous mechanical ventilation, the second calibration measurement after a swich to a mandatory mode. Two Pes catheters will be tested

### Study burden and risks

Risk is nihil. Patients are sedated and the burden is also nihil. The increase in sedation and possible use of neuromuscular blockade could possibly extend the length of ICU stay. However this is estimated as without clinical consequences.

## Contacts

**Public**
Leids Universitair Medisch Centrum

Albinsudreef 2
Leiden 2333 ZA
NL
**Scientific**
Leids Universitair Medisch Centrum

Albinsudreef 2
Leiden 2333 ZA
NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

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

### Inclusion criteria

Estimated Mechanical ventilation time > 24 hrs
Spontaneous mechanical ventilation
Esophageal balloon catheter in situ
Sedated RASS -5

### Exclusion criteria

Contraindication for insertion of a Pes catheter (esophageal varices, other esophageal pathology)
Awake

## Study design

### Design

| | |
|---|---|
| Study type: | Observational invasive |
| Intervention model: | Other |
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Other |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-06-2024 |
| Enrollment: | 40 |
| Type: | Anticipated |

### Medical products/devices used

| | |
|---|---|
| Generic name: | Esophageal balloon catheter |
| Registration: | Yes - CE intended use |

# Ethics review

| | |
|---|---|
| Approved WMO Date: | 23-07-2024 |
| Application type: | First submission |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden) |
| | metc-ldd@lumc.nl |

# 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 |
|---|---|
| CCMO | NL83335.058.24 |