# The value of repeated BIOMarker measurements during an SBT to predict EXtubation failure in mechanically ventilated ICU patients

Published: 16-02-2022
Last updated: 28-09-2024

To investigate the association of biomarker measurements (NT-proBNP, hsTroponin-T, CKMB, myoglobin, GDF-15, CRP, IL-6, IL-10, PCT, galectin-3, ST-2, albumin) during an SBT with extubation failure in mechanically ventilated ICU patients.

| | |
|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Heart failures |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON54189

**Source**
ToetsingOnline

**Brief title**
The BIOMEXIC study

### Condition

- Heart failures
- Lower respiratory tract disorders (excl obstruction and infection)

**Synonym**
extubation failure, Mechanical ventilation

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Erasmus MC, Universitair Medisch Centrum Rotterdam
**Source(s) of monetary or material Support:** Ministerie van OC&W,Roche Diagnostics International Ltd

## Intervention

**Keyword:** Biomarkers, Extubation failure, ICU, Mechanical ventilation

## Outcome measures

### Primary outcome

Extubation failure within 7 days, composed of:

- Reintubation, or

- All-cause mortality

### Secondary outcome

- Extubation failure within 48 and 72 hours

- Rescue non-invasive ventilation or high-flow nasal oxygen for post-extubation respiratory insufficiency, or

- ICU length of stay post-extubation for medical reasons

- ICU re-admission rate within current hospitalization

- All-cause mortality: ICU, 28-days, hospital, 3 and 12 months

- Long-term follow-up at 3 and 12 months: major adverse cardiovascular events (total death, myocardial infarction, coronary revascularization, stroke, and hospitalization because of heart failure or arrhythmia), Quality of life (RAND-36 and EQ-5D questionnaires).

# Study description

### Background summary

In order to prevent extubation failure or unnecessary prolonged ventilation, accurately predicting readiness for extubation is of key importance in ICU care. Currently, clinical criteria and spontaneous breathing trials (SBTs) are used to assess readiness for extubation. Data on the prognostic value of biomarkers in this setting are limited.

A more detailed description of the study background is provided on page 8 of the C1 research protocol.

### Study objective

To investigate the association of biomarker measurements (NT-proBNP, hsTroponin-T, CKMB, myoglobin, GDF-15, CRP, IL-6, IL-10, PCT, galectin-3, ST-2, albumin) during an SBT with extubation failure in mechanically ventilated ICU patients.

### Study design

Multi-centre prospective observational cohort study.

### Study burden and risks

This study will collect data that is clinically available, but also encompasses repeated biomarker measurements, cardiopulmonary echographic examination and electrocardiography. Because almost all mechanically ventilated ICU patients have an arterial line, blood can be easily sampled without venepuncture and poses negligible risks for the study patients.

## Contacts

**Public**
Erasmus MC, Universitair Medisch Centrum Rotterdam

Hoevestraat 25B
Rotterdam 3033 GB
NL
**Scientific**
Erasmus MC, Universitair Medisch Centrum Rotterdam

Hoevestraat 25B
Rotterdam 3033 GB
NL

# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

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

## Inclusion criteria

- Aged >=18 years
- Mechanically ventilated for more than 48 hours
- Fulfilling readiness-to wean criteria (ref. no. 12 in C1 research protocol)
- Written informed consent from the patient or his/her legal representative

## Exclusion criteria

- Patients with risk factors for laryngeal edema and a negative cuff leak test (indicating upper airway obstruction with need for steroid treatment)
- Planned replacement of the endotracheal tube for a tracheostomy
- Terminal illness
- Pregnancy

# Study design

## Design

**Study type:** Observational invasive

| | |
|---|---|
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Basic science |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 01-08-2022 |
| Enrollment: | 266 |
| Type: | Actual |

## Ethics review

| | |
|---|---|
| Approved WMO Date: | 16-02-2022 |
| Application type: | First submission |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |
| Approved WMO Date: | 17-07-2023 |
| Application type: | Amendment |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |
| Approved WMO Date: | 19-09-2024 |
| Application type: | Amendment |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |

## Study registrations

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

No registrations found.

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

ID: 25054
Source: Nationaal Trial Register
Title:

## In other registers

| Register | ID |
| --- | --- |
| ClinicalTrials.gov | NCT05637099 |
| CCMO | NL77372.078.21 |