

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: NTR
Title:

5 - The value of repeated BIOMarker measurements during an SBT to predict EXtubation ... 7-05-2025

In other registers

Register

ClinicalTrials.gov

CCMO

ID

NCT05637099

NL77372.078.21