Herhaalde biomarker metingen rondom extubatie op de Intensive Care

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON25054

Source
Nationaal Trial Register

Brief title
The BIOMEXIC study

Health condition

Adult patients admitted to the ICU who are mechanically ventilated for >24h.

Sponsors and support

Primary sponsor: Roche Diagnostics International Ltd
Source(s) of monetary or material Support: Roche Diagnostics International Ltd

Intervention

Outcome measures

Primary outcome

Extubation failure within 48 hours, composed of:
- Reintubation, or
- Rescue non-invasive ventilation or high-flow nasal oxygen for post-extubation respiratory insuf-ficiency, or

- All-cause mortality

Secondary outcome

- Extubation failure within 72h and 1 week
- ICU length of stay post-extubation for medical reasons
- ICU re-admission rate within current hospitalisation
- 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).

Study description

Background summary

Rationale: In order to prevent extubation failure or unnecessary prolonged ventilation, accurately predicting readiness for extubation is of key importance in the ICU. 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.
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 population: Adult ICU patients who are mechanically ventilated for >24h and fulfil readiness-to wean criteria.
Main study parameters/endpoints: Extubation failure (the need for reintubation within 48 hours).
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: This study will collect data that is clinically available, but also encompasses repeated biomarker measurements and cardiopulmonary echographic examination. 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.

Study objective

The aim of this study is to investigate the association between biomarkers that reflect various pathophysiological mechanisms (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. Moreover, we will investigate the association of these biomarkers with long-term outcome after extubation. This could improve the prediction of readiness for extubation, and may direct post-ICU care in this vulnerable population.
The temporal evolution of these biomarkers during an SBT and extubation will be related to cardiopulmonary echography, in order to further elucidate the structural and functional

changes in the failure-to-wean heart. Ultimately, this may direct novel treatment strategies to safely shorten duration of mechanical ventilation and to improve outcome after extubation.

Study design

- 48 hours, 72 hours, 1 week, 28 days, 3 and 12 months after extubation
- ICU discharge, hospital discharge

Intervention

Not applicable.

Contacts

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Eligibility criteria

Inclusion criteria

- Aged ≥18 years
- Mechanically ventilated for >24h
- Fulfilling readiness-to wean criteria
- Written informed consent from the patient or his/her first representative

Exclusion criteria

- Patients with risk factors for laryngeal oedema and a negative cuff leak test, performed after a successful SBT (indicating upper airway obstruction with need for steroid treatment)
- Planned replacement of the endotracheal tube for a tracheostomy

- Terminal illness

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2021
Enrollment:	266
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 54189
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL9286
CCMO	NL77372.078.21
OMON	NL-OMON54189

Study results