Herhaalde biomarker metingen rondom extubatie op de Intensive Care

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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...

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON25054

Bron
NTR

Verkorte titel
The BIOMEXIC study

Aandoening

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

Ondersteuning

Primaire sponsor: Roche Diagnostics International Ltd
Overige ondersteuning: Roche Diagnostics International Ltd

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

Not applicable.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-10-2021
Aantal proefpersonen:	266
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 54189
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten