Prospective Observational study Comparing Electromyography of the Diaphragm with Ultrasound in neonates and children with Respiratory Support: the PROCEDURES study

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Our objective is to assess the association between transcutaneous diaphragm electromyography (dEMG) and diaphragm ultrasound (dUS) in the PICU population.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Musculoskeletal and connective tissue disorders NEC
Study type	Observational non invasive

Summary

ID

NL-OMON53611

Source
ToetsingOnline

Brief title
the PROCEDURES study

Condition

- Musculoskeletal and connective tissue disorders NEC
- Respiratory disorders NEC

Synonym
diaphragm function, midriff function

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Diaphragm, Electromyography, Ultrasound

Outcome measures

Primary outcome

Primary endpoint is to evaluate the association between dEMG and dUS

measurements in the PICU population.

Secondary outcome

not applicable

Study description

Background summary

Increased work of breathing, potentially leading to respiratory insufficiency, resulting in the need of (non-) invasive respiratory support is the most common observed problem in the neonatal - and pediatric intensive care unit (NICU/PICU). The diaphragm is the main respiratory muscle. Currently there is not an established technique accessible to observe the (clinical) function of the diaphragm and its role in respiratory insufficiency. New non-invasive modalities are promising, such as transcutaneous diaphragm electromyography (dEMG) and diaphragm ultrasound (dUS).

Study objective

Our objective is to assess the association between transcutaneous diaphragm electromyography (dEMG) and diaphragm ultrasound (dUS) in the PICU population.

Study design

Single center pilot study

Study burden and risks

This study can only be performed within the infant and pediatric intensive care population due the specific challenges seen in these patients as result of the physiological immaturity of the respiratory system and immature lung development in this specific population. As well the small size of the patients with specific challenges of the precision of dEMG and dUS.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Babies and toddlers (28 days-23 months)

Inclusion criteria

Patients admitted at the pediatric intensive care unit
Age between 0 - 12 months of age at the moment of inclusion
Patients with invasive respiratory support that meet extubation readiness test (ERT) criteria
A patient can only participate once

Exclusion criteria

- No spontaneous breathing for the duration of the assessment
- Unilateral diaphragm paresis
- Congenital malformations not compatible with transcutaneous EMG
- Congenital muscle atrophy disorder
- The attending physician considers the patient to be too vulnerable to participate in the study

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	29-11-2023
Enrollment:	50
Type:	Actual

Medical products/devices used

Generic name:	Ultrasound machine
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	25-05-2023
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	NL83049.058.23