Changes of the right diaphragmatic kinetics following tracheal extubation in the newborn by using pulsed tissue Doppler imaging: a pilot study. (ET RD-PTDI neo)

First published: 16/11/2023

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Study Ongoing

Administrative details

EU PAS number

EUPAS107663

Study ID

108118

DARWIN EU® study

No

Study countries

☐ Italy

Study description

This is an observational, non-interventional cohort pilot study. Our objective is to describe potential changes in right diaphragm kinetics, if any, using pulsed-wave tissue Doppler imaging after extubation and withdrawal of mechanical ventilation in the newborn. The results of this pilot study will provide indications for a subsequent study in case of changes in diaphragmatic kinetics predictive of extubation failure (defined as the need to restore mechanical ventilation within 72 hours of extubation due to respiratory failure), for validation in an adequate sample of newborns.

Study status

Ongoing

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Radicioni Maurizo

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 15/11/2023

Study start date

Planned: 15/11/2023

Actual: 11/12/2023

Date of final study report
Planned: 11/11/2024

Sources of funding

- Other

More details on funding

No funding

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Main study objective:

To ascertain whether early signs of diaphragmatic dysfunction predictive of tracheal extubation failure (defined as the need to restore mechanical ventilation within 72 hours of extubation due to respiratory failure) can be identified with bedside ultrasound.

Study Design

Non-interventional study design

Other

Population studied

Age groups

- Preterm newborn infants (0 – 27 days)
- Term newborn infants (0 – 27 days)

Estimated number of subjects

50

Study design details

Data analysis plan

The Shapiro-Wilk test will be used to assess normal distribution of variables, Chi-square test with Yate’s continuity correction and Fisher’s exact test for

comparisons of categorical variables, and Mann–Whitney’s U for non-normally distributed continuous variables. Relationships between variables will be tested using the Spearman rho correlation coefficient analysis. Statistical analyses will be performed using IBMSPSS VR version 26.0 (IBM Corp. Armonk, NY, USA, 2019), and a two-sided P value < 0.05 will be considered significant.

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Other

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No